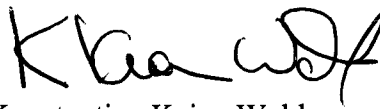## COPYRIGHT AND POSITION CERTIFICATION

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An Assessment of Health Literacy Rates in a Sample of Active-Duty
Military Personnel at a Major Medical Center

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Acknowledgement

DISSERTATION DOSSIER
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LINKING PAPER/EXECUTIVE SUMMARY:
AN ASSESSMENT OF HEALTH LITERACY RATES IN A SAMPLE OF ACTIVE-
DUTY MILITARY PERSONNEL AT A MAJOR MEDICAL CENTER

KONSTANTINE KEIAN WELD, CAPT, USPHS

According to the Institute of Medicine's (IOM) report, Health Literacy: A Prescription to

End Confusion, at least one-third of the United States population suffers from limited health

literacy. Limited health literacy prevents patients from effectively using their respective health

systems and has been linked to health disparities, poorer health status, and lower use of

preventive services. Higher rates of limited health literacy have also been found in non-Whites

and individuals with lower education levels and/or incomes, or who lack access to health care.

The IOM has noted that active-duty military personnel, particularly new recruits, may be

at risk for limited health literacy. The IOM has also recommended that the Department of

Defense (DoD) develop programs to reduce the negative effects of limited health literacy.

However, to date there are no published research studies describing health literacy rates in the

active-duty military population. To address this gap, a descriptive study was conducted at a

major military medical center to examine the health literacy rates among a sample of active-duty

military personnel receiving health care within a culture of universal access.

Universal access to health care is characterized as having both financial (health insurance

coverage) and structural access to care as well as lack of personal barriers to care such as cultural

or sociological attitudes and perceptions. Structural access to care exists when an individual has

a regular place of health care such as the Military Health System (MHS). In the MHS, the ability

of active-duty military personnel to obtain health information and services needed to make

appropriate health decisions, and improve health status is equal. However, even though active-

duty military personnel have financial and structural access to care, there may be individual or

personal barriers to health care among individual service members that affect health literacy rates and associated outcomes (health disparities, health services, use of preventive services).

The three specific aims of this study were to: (1) identify the literacy skills and health literacy skills in a sample of active-duty military personnel using the Rapid Estimate of Literacy in Adults (REALM) and the Short – Test of Functional Health Literacy in Adults (S-TOFHLA), respectively, (2) examine the relationship between limited health literacy skills and gender, race/ethnicity, pay grade/rank, age, education level, and marital status; and (3) evaluate the reliability, validity, and practicality of the STOFHLA in a sample of active-duty military personnel.

The first manuscript in this dissertation dossier is the manuscript of excellence which was submitted prior to the dissertation proposal being approved. The manuscript is a concept analysis of malpractice and modern day nursing practice. While the manuscript is not specifically focused on health literacy, the impact of limited health literacy on patient care in terms of potential adverse events and patient safety is an important consideration for clinical nursing practice.

The second manuscript examines the evolution and current state of the science of health literacy from its roots in literacy to the present. This examination reaffirmed the principle that improving health literacy is recognized as a means of empowering patients with resulting improvements in individual health status and patient safety. The third manuscript explores the concept of health literacy further by describing theoretical frameworks that can be used to guide health literacy research in population groups with universal access to care and identifying implications for nursing research and practice related to an adaptation of a framework developed specifically for conducting research in populations with universal access to health care. The

fourth and fifth manuscripts are directly related to the three specific aims of the dissertation research study.

The fourth manuscript addresses the first and third specific aims. Using the REALM and S-TOFHLA, data were collected from a sample of 155 active-duty participants from January through May 2007. Results were encouraging and revealed that 99% of participants had adequate health literacy skills. However, significant differences in S-TOFHLA scores were noted for health professional training (p = .000) and race/ethnicity [F(3, 43)= 5.7, p =.002] with specific post-hoc comparisons revealing a difference between African Americans and White subgroups (p = .000). While reliability and validity testing for the STOFHLA was moderately low, the S-TOFHLA was found to be efficient tool for assessing health literacy in a high-tempo, military health care setting.

The final manuscript describes the relationship between health literacy and sociodemographic characteristics (SDCs) in a sample of personnel within a culture of universal access to care. Analyses were conducted using linear regression. Of the 7 SDCs (gender, age, race/ethnicity, marital status, education level, health training, pay grade/rank), health training and being African American were the only significant predictors of health literacy skill level (p = .000). As reflected in Healthy People 2010, closing the gap in health literacy skills among racial/ethnic groups is essential to reducing health disparities occurring at varying levels of access, including universal access to care. Results from this dissertation research support the need to further explore relationships between health literacy and SDCs in a variety of populations and settings. Even when financial access and structural access were equal, noneconomic disparities existed in this sample of active-duty military personnel.

Chapter 2. Manuscript of Excellence

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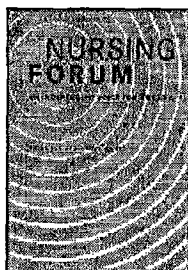
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AUTHOR'S PAGE

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Introduction

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ABSTRACT

Topic. The concept of malpractice can mean different things depending upon the context in which the term is used. This can lead to confusion about the standard of care required for nurses engaged in modern day nursing practice.

Purpose. This paper examines the attributes and characteristics of the concept of malpractice using Walker and Avant's (1995) eight step methodology.

Source(s) of Information. CINAHL, PubMed, and PsychINFO.

Conclusions. Exposure to malpractice liability is an unfortunate consequence of modern day nursing practice. An understanding of malpractice will assist nurses in identifying situations that may expose them to legal liability and hopefully lead to improved patient care.

Search Terms: concept analysis, malpractice, negligence, competency

SUMMARY

What is already known about this topic

- Malpractice is a concept whose meaning is contextual and often used interchangeably with negligence, and incompetent nursing care

- The concept of malpractice cannot be divorced form modern day nursing practice regardless of practice area and location of practice

What this paper adds

- A conceptual definition of malpractice based upon multiple definitions and usages of the concept

- Implications of the analysis for nursing practice regardless of practice area and location of practice

Introduction

In the last four decades, the role of registered nurses has evolved from that of a passive, servile employee to that of an assertive, decisive health care provider (*Bleiler v. Bodnar*, 1985). Today, registered nurses monitor complex physiological data, operate sophisticated lifesaving equipment, coordinate the delivery of a myriad of patient services, and administer multi-million dollar health care programs (*Bleiler v. Bodnar*, 1985). Indeed, registered nurses have more professional accountability than at any other time in the history of nursing. As a result, nurses must confront the fact that they now owe a higher duty of care to their patients, and by extension, are more exposed to civil claims for negligence than every before.

While the concept of malpractice may not be as pleasant a topic to analyze as other concepts such as "patient satisfaction" or "caring," it is nonetheless an important concept for all nurses to consider. In fact, few concepts have a more significant impact on the profession of nursing, patient and non-patient practice areas alike, than the concept of malpractice. However, an online search in the databases Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, and PsychINFO failed to identify a single concept analysis for either malpractice or negligence. Interestingly enough, the search also did not yield a single concept analysis for either the terms competent or incompetent. Accordingly, the purpose of this concept analysis is to initiate a professional dialogue about the concept of malpractice and to clarify the ambiguities surrounding the concept's use in nursing practice. Doing so should assist nurses in gaining a greater understanding of what it means to commit malpractice and how this raised awareness can lead to improved patient care.

Concept Analysis

According to Walker and Avant (1995), concept analysis is a strategy for examining the attributes or characteristics of a concept. Restated, concept analysis is an analytical tool used for distinguishing between the defining attributes of a concept and its irrelevant ones. Walker and Avant (1995) also contend that concept analysis is useful for a number of other reasons including to help clarify overused vague concepts such as malpractice so that nurses who "subsequently use the term will be speaking of the same thing" and to provide a precise operational definition.

The organizing framework for this concept analysis is the eleven-step model developed by Wilson (1963) and later simplified to eight steps by Walker and Avant (1995). The eight steps are as follows: 1) select a concept for study; 2) identify the purpose of the concept analysis; 3) identify uses of the concept; 4) determine defining attributes; 5) develop a model case; 6) construct additional borderline, related, contrary, invented, and illegitimate cases; 7) identify antecedents and consequences; and finally, 8) define empirical referents. The first two steps have been addressed above, and will not be restated although the purpose of this concept analysis will be explored throughout this analysis. As for the remaining six steps, they will be covered in the same order as listed with the caveat that after the model case is developed, only one additional case will be constructed- the contrary case.

The Concept of Malpractice- Identified Uses

To identify the uses associated with the concept of malpractice, it is advisable to begin with an explanation as to how the concepts of malpractice and negligence differ. While these two concepts are often used interchangeably in nursing,

and sometimes legal literature as well, they are distinctive concepts in their own right. Negligence as defined by Black's Law Dictionary (1979) and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) (2002) is the "failure to use such care as a reasonably prudent and careful person would use under similar circumstances." It is the predominant theory of liability in medical malpractice litigation (King, 1986).

In contrast, the concept of malpractice is often used to embrace all liability producing conduct arising from the rendition of professional services including, but not limited to: negligence, intentional misconduct, breaches of contracts guaranteeing a specific therapeutic result, divulgence of confidential information, unauthorized postmortem procedures, failures to prevent injuries to certain non-patients, and defamation (King, 1986). This approach to malpractice is reflected in the concept's definition as set forth in Black's Law Dictionary (1979) which defines malpractice as professional misconduct or unreasonable lack of skill. JCAHO also defines malpractice in this same manner (JCAHO, 2002). Similarly, Barron's Law Dictionary (1991) defines malpractice as a professional's improper or immoral conduct in the performance of duties, either intentionally, through carelessness, or through ignorance. Moreover, even in a lay dictionary such as The American Heritage Dictionary (2001), the concept of malpractice is distinguished from the term negligence by defining the former as improper, negligent, or unethical conduct or treatment and the latter as essentially the same as set forth in Black's Law Dictionary (1979). Thus, as a basic rule and in terms of common usage, the concept of malpractice is clearly a more expansive than the concept of negligence.

Although more expansive, the concept of malpractice is so intimately related to the concept of negligence that from the standpoint of identifiable uses, the concepts are at times practically indistinguishable. The reason for this is that in the health care field, the concept of malpractice traditionally encompassed only the negligent acts of physicians because as indicated above, nurses were viewed as passive, servile employees. The tasks performed by nurses were considered so basic that even non-nurses could understand them and thus, plaintiffs were allowed to assess liability against nurses pursuant to the basic theory of negligence, i.e., reasonable person standard (Cavico & Cavico, 1995). Today however, nurses are viewed in a different light. As assertive, decisive health care providers, liability for basic nursing negligence has begun to shift to its professional counterpart- malpractice liability; and with this shift, nurses are now held to a more demanding professional standard of care (*King v ex rel. Department of Health & Hosps*, 1999). Accordingly, this means the concept of malpractice as applied to professional nurses is also an identifiable theory of civil liability, and for purposes of this conceptual analysis- an identifiable use.

In addition to the concept's use as a legal theory, it also has identifiable uses at the practice level as well. However, these manifestations of the concept are not always explicitly identified as "malpractice." Rather, many times the concept of malpractice is identified by a synonym such as clinical negligence, poor quality nursing care, or professional incompetency. When this is happens, the conceptual focus of the concept shifts from being on the civil litigation arena to one focused on the every day practice nursing where it is used to illuminate the point where nursing practice passes from being competent or acceptable to incompetent and unacceptable.

As example of this shift is seen in section 65-1120(e) of the Kansas Nurse Practice Act (KNPA)) where Kansas state legislature identified the demarcation line between competency and incompetency with great specificity. The KNPA defines professional incompetency as:

    (1) One or more instances involving failure to adhere to the applicable standard of care to a degree which constitutes gross negligence, as determined by the board;

    (2) Repeated instances involving failure to adhere to the applicable standard of care to a degree which constitutes ordinary negligence, as determined by the board; or

    (3) A pattern of practice or other behavior which demonstrates a manifest incapacity or incompetence to practice nursing (K.S.A. 65-1120(e), 2003).

Thus, even though the KNPA does not mention the term malpractice, it is clear from section 65-1120(e) that the concepts of professional incompetency, malpractice, and even clinical negligence, are essentially one and the same with respect to the KNPA. More importantly however, once it is understood that the concepts of clinical negligence and professional incompetency are a proxy for the concept of malpractice, it becomes much easier to identify additional uses of the concept in nursing, health care, and legal literature.

For instance, after finding that nursing literature does not provide a clear definition of nursing competency, attorney Mustard (2002) decided to define the opposite of professional competency, i.e., incompetency or malpractice. To do so, Mustard (2002) reviewed 200 of his firm's cases that involved nursing actions that resulted in patient

injury. As expected, the review resulted in a litany of nursing actions that are reflective malpractice such as a failure to adequately assess and monitor patients and poor technical proficiency in the performance of nursing duties. In addition, he was able to identify patterns of nursing actions that led to malpractice such as a lack of thoroughness and poor self-control skills combined with a lack of critical thinking skills. However, the most important aspect of this exercise was that Mustard (2002) was able to use the concept of malpractice: to identify and assess competency within the nursing profession; and to identify recommendations regarding educational and management techniques that might lead to greater competency and better patient care in the hospital acute care setting.

Similarly, the concept of malpractice has been used to influence the theory and practice of risk management and along with it, nursing practice. For example, Roy (1996) used a case study involving the concept of clinical negligence, i.e., malpractice, to illustrate how a failure to apply risk management techniques could adversely affect the clinical setting. In using the concept of malpractice, Roy (1996) was able to demonstrate how nurses could identify risk management issues use this knowledge to further the use of risk management techniques in their own organizations. Likewise, Koniak-Griffin (1999) used the concept of malpractice to develop strategies for reducing the risk of claims for clinical negligence in perinatal nursing. As with Roy (1996), Koniak-Griffin (1999) was able to identify risk management techniques that should lead to improved patient care while decreasing the prevalence of nursing incompetence.

Finally, the concept of malpractice has been used for the purpose of improving basic nursing care. For example, Mahlmeister (2000) utilized the concept in her exploration of the legal implications involved in fetal heart assessment. In doing so, she educated the

nursing community as to the applicable standard of care that nurses should use in fetal

heart assessment and the consequences of not doing so, both clinically and professionally.

Likewise, Mahlmeister and Konisk-Griffin (1999) used the concept of malpractice as a

platform to review the professional accountability and legal liability for the team leader

and charge nurse. In addition, they also educated the nursing community as to applicable

standard of care and set forth strategies for enhancing individual nurse accountability

while reducing exposure to a finding of professional incompetency and/or civil liability.

Defining attributes

Although it is possible to define malpractice in an expansive manner, for purposes

of this concept analysis, "malpractice" is defined as an unreasonable lack of professional

skill by a professional registered nurse. Its defining attributes are as follows:

1.   The person must be a registered nurse;

2.   The conduct in question must take place while the person is acting in his/her

        capacity as a registered nurse;

3.   The conduct in question represents manifest incompetence or an unreasonable

        lack of professional skill in the nursing practice.

As one can see, inherent in both the definition of malpractice and the concept's

defining attributes is the requirement that the standard of conduct and/or competency for

nursing practice be identifiable. However, as both the author and Mustard (2002)

discovered in their survey of nursing literature, absent a determination by a judicial or

regulatory body that conduct is substandard, it can be difficult to identify the standard of

conduct that establishes the line between competent and incompetent nursing care.

Indeed, even a review of information contained in the National Practitioner Data Bank

does not appear helpful in eliminating this difficulty (Faherty, 1998). As a result, this concept analysis will address this concern by refining the critical attributes of malpractice through the identification of the concept's antecedents and consequences as set forth after the case constructions (Walker & Avant (1995).

Case Construction

Developing cases is another technique that enhances the process of concept analysis. For example, a model case may be developed in order to provide a real life scenario where all the defining attributed are evident. In addition, a contrary case may be developed to present a scenario that clearly does not represent the concept being analyzed (Walker & Avant, 1995).

Model Case

A five-month old infant has been in the neonatal intensive care unit (ICU) since birth. The registered (ICU) nurse notices that she experiences a drop in her potassium level. After notifying the on-call resident and receiving an order for potassium chloride, the registered nurse administers ten times the prescribed dose intravenously. Staff efforts to resuscitate the infant fail and the she dies one week later. The hospital investigates the matter and finds that in addition to the dose being administered incorrectly, potassium chloride was not on the hospital's list of medications that could be administered intravenously by nursing staff. The nurse's conduct was clinically incompetent.

Contrary Case

A professional registered nurse working on a surgical ward receives an order from the surgeon to administer intravenous morphine to an adult male patient. The nurse verifies the order with another staff member and reviews the hospital policy to ensure that

nurses are authorized to administer the medication intravenously. After ensuring that she is authorized to administer the medication, the nurse does so. Afterwards, the nurse assesses the patient's vital signs pursuant to guidelines established for her unit.

<div align="center">Antecedents and Consequences Identified</div>

As indicated above, the antecedents and consequences of malpractice will be identified as a way of further refining the concept's defining attributes. This process of identification is a way of shedding additional light on the social contexts in which the concept of malpractice occurs (Walker and Avant, 1995).

Antecedents

Antecedents are those events, incidents, or behaviors that must occur before the concept of malpractice takes place (Walker and Avant, 1995). Hence, when analyzing the concept of malpractice, it is necessary to identify those events, incidents, or behaviors that cause or contribute to the provision of substandard care by a registered nurse in the work place. Of course, this is not an easy task as there may be a number of reasons that a registered nurse has an unreasonable lack of professional skill. Nevertheless, a review of both nursing and legal literature suggests there are two antecedents that occur either alone or in concert, before all occurrences of malpractice. The two major antecedents are as follows: lack of adequate education and training; and lack of thoroughness and attention to detail on behalf of the nurse.

The first antecedent to malpractice is a lack of adequate education and training for the practice areas in which the nurse's work. For instance, nurses who work in a clinical area and lack fundamental information and knowledge about the medication(s) they are

responsible for administering are at high risk for providing incompetent or substandard

care. This is exactly what happened in the case of *Polansky v. Union Hospital*, (1981),

whereby a hospital was found liable for injuries caused to a patient due in part to the

nurse's lack of understanding about the risks of administering a sleeping drug to an

elderly patient. In addition, nurses have also been found to have engaged in substandard

care where they did not know how to operate equipment properly or used it in a way that

was contraindicated (Eskreis, 1998). Finally, even nurses who are not the primary care

provider are at risk for malpractice if they lack adequate education and training. For

example, Mahlmeister and Koniak-Griffin (1999) have noted that team leaders and

charge nurses have a duty to report dangerous unit conditions that might compromise

patient care. Hence, team leaders and charge nurses need to have a proper educational

and training background in order to fulfill their roles in a safe, effective manner.

The second antecedent is a lack of thoroughness or attention to detail by the nurse

while engaged in nursing practice. This antecedent is clearly related to the first

antecedent in that a lack of education and training is certainly a factor that can contribute

to a nurse's lack thoroughness or attention to detail. However, this antecedent is also a

separate behavior in that even an educated and trained nurse can exhibit a lack of

thoroughness or attention to detail. In either case, one area where this antecedent is

routinely spotted is in the area of nursing documentation. For example, nurses who fail

to properly document where they administered a shot may be liable for patient injuries

that are associated with the shot if the nurse failed to document critical nursing

information or events (Croke, 2003). Similarly, in *Brown v. E.A. Conway Memorial*

Hosp. (1991) the court found that the possibility that a knife blade had broken off in a

patient's shoulder was significant and should have been reported by a nurse to the attending physician.

Consequences

Consequences are the events or incidents that occur as a result of the occurrence of malpractice (Walker & Avant, 1995). Restated, consequences are the outcomes that stem from the concept's occurrence. In the context of malpractice, these are somewhat easier to identify than the concept's antecedents. After reviewing both nursing and legal literature, the author was able to identify six consequences.

First, the most tragic consequence that can result from an episode of malpractice is injury or death to the patient. Moreover, even if the patient is not physically injured, the patient could still suffer psychological trauma as a result of malpractice. Second, both the patient and the nurse could lose money. The patient could lose money as a result of experiencing an increase in medical bills or his/her inability to return to work- lost wages. The nurse could also lose money if he/she is fired or suspended from work on account engaging in malpractice, or if a legal judgment is successfully brought again the person (Schmidt & McCartney, 2000). Third, the nurse may experience a diminution in reputation due to the occurrence of malpractice that could also have negative financial ramifications just as an inability to get rehired.

Fourth, if the occurrence of malpractice is egregious enough, the nurse could be charged with criminal negligent homicide (Schmidt & McCartney, 2000). Fifth, the hospital may also lose money and/or reputation due to the occurrence of nursing malpractice and this could impact the nursing and patient community alike. Sixth, and finally, there may also be a positive consequence that results from the occurrence of the

malpractice. Specifically, the occurrence of malpractice may act as a catalyst for the nursing profession to improve nursing competencies at both the individual and institutional level. Indeed, as Mustard (2002) noted, the ability to define what is a "competent nurse" is quite difficult. As a result, it is imperative that nursing profession continue to seek improvement in this area by developing universal competencies as JCAHO is trying to do.

<div align="center">Define Empirical Referents</div>

The final step in the concept analysis is to define the empirical referents. Empirical referents are classes or categories of actual phenomena that that bear witness to the existence of the concept in the real world (Walker & Avant, 1995). Since malpractice is defined in this concept in behavioral terms, categories or classes of behavior or a regulatory proxy, will be used to measure the concept and by doing so, provide greater clarity to the concept's critical attributes. In addition, this approach will further an understanding of this analysis's discussion on the antecedents of malpractice.

The most obvious measure of whether malpractice as defined in this analysis has occurred is by determining whether a judicial or regulatory body has made a civil or criminal determination of malpractice against an individual nurse. If so, it is a clear demonstration that malpractice has occurred. Reported entries to the National Practitioner Data Bank are also a measure of individual nursing malpractice with the caveat that there is debate as to the usefulness of this information (Faherty, 1998).

In addition, it is possible to conceive of many potential behavioral categories that may reflect the fact that malpractice has occurred. However, based upon a review of nursing and legal literature, it was determined that there are six categories of behavior

that if identified in nursing practice, would always reflect the occurrence of malpractice as define in this analysis (Eskreis, 1998). The six behavioral categories for measuring the occurrence of nursing malpractice are as follows:

1. Documented medication errors- where the nurse does not properly administer medication to a patient for any reason, e.g., incorrect dose, route, time.

2. Failure to follow physician orders or established protocols or policies;

3. Improper use of equipment or technology;

4. Failure to remove foreign objects from the patient;

5. Failure to provide sufficient monitoring and assessment of the patient; and

6. Failure to communicate, notify and/or report key nursing information in a proper and timely manner.

<div align="center">Summary of Analysis and Conclusion</div>

Although the concept of malpractice may make some nurses uneasy, it is essential for nurses to know about the concept in today's nursing environment. This concept analysis furthers this goal by providing insight into the concept of malpractice and by identifying specific scenarios where unacceptable nursing care may exist. These scenarios should not however, be seen as devices to catch "bad nurses." Rather, the nursing community should embrace these new insights into the concept of malpractice and use them develop educational and training methods to improve patient care and decrease the likelihood of malpractice occurring. Doing so should lead to improve patient care and reduced liability for nurses – whether in general or advanced practice nurses and nurse researchers in particular.

References

The American Heritage Dictionary 4th Ed (2001). New York, NY: Dell.

Barron's Law Dictionary (1991) Gifis, S.H. ed. Hauppauge, NY: Barron's Educational

Series.

Black's Law Dictionary (1979) Publisher's Staff ed. St. Paul, Minn: West.

Bleiler v. Bodnar, 65 N.Y2d. 65, 479 N.E.2d 230 (1985).

Brown v. E.A. Conway Memorial Hosp. (1991). 588 So. 2d 1295, 1991 La. App. Lexis

2828

Cavico, F.J. & Cavico, N.M. (1995) The nursing profession in the 1990's: negligence

and malpractice liability. *Cleveland State Law Review, 43,* 557-626.

Croke, E. M. (2003). Nurses, negligence, and malpractice: an analysis based on more

than 250 cases against nurses. *American Journal of Nursing,103(9),* 54-63.

Eskreis, T. (1998). Seven common legal pitfalls in nursing. *American Journal of Nursing,*

98(4), 34-40.

Fahery, B. (1998). Medical malpractice and adverse actions against nurses: five years of

information from the National Practitioner Data Bank. *Journal of Nursing Law,*

5(1), 17-25.

Joint Commission on Accreditation of Healthcare Organizations (2002) Hospitals-

Sentinel Event Glossary of Terms. http://www.jcaho.org.

Kansas Nurse Practice Act. K.S.A. 65-1120(e) (2003).

Koniak-Griffin, D. (1999). Strategies for reducing the risk of malpractice litigation in

perinatal nursing. *Journal of Obstetric, Gynecologic, & Neonatal Nursing, 28(3),*

291-299.

King J.H. (1986). *The law of medical malpractice in a nutshell* 2nd ed. St. Paul, Minn:
West.

King v. State ex rel., Department of Health & Hosps., *La.* App. 31651, 728 So. 2d 1027,
1999 La. App. LEXIS 436 (La.App. 2 Cir. Feb. 24, 1999); writ denied La. 99-
0895, 741 So. 2d 656, 1999 La. LEXIS 1415 (La. May 7, 1999).

Mahlmeister, L. (2000). Legal implications of fetal heart assessment. *Journal of*
Obstetric, Gynecologic, and Neonatal Nursing, 29(5), 517-526.

Mahlmeister, L. & Konisk-Griffin, D. (1999). Professional accountability and legal
liability for the team leader and charge nurse. *Journal of Obstetric, Gynecologic,*
and Neonatal Nursing, 28(3), 300-309.

Mustard, L. (2002). Caring and competency. *Journal of Nursing Administration's*
Heathcare, Law, Ethics, and Regulation, 4(2), 36-43.

Polansk v. Union Hospital (1981). 11 Mass. App. Ct. 622; 418 N.E.2d 620; Mass. App.
LEXIS 1005

Roy, S. (1996). Risk management. *Nurse Standard, 10(18),* 51-56.

Schmidt, J.V. & McCharney, P.R. (2002). Legal implications of fetal heart assessment.
Journal of Obstetric, Gynecologic, and Neonatal Nursing, 29(5), 517-520.

Walker, O.W., & Avant, K.C. (1995) *Strategies for theory construction in nursing*
Norwalk, CT: Appleton & Lange.

Wilson, J. (1963). *Thinking with concepts.* Cambridge, MA: Cambridge University
Press.

Chapter 3. Proposal

ASSESSMENT OF HEALTH LITERACY RATES
IN A SAMPLE OF ACTIVE-DUTY MILITARY PERSONNEL

ECTION A.   Specific Aims

At least one-third of the population lacks the health literacy skills to effectively use their respective health system. Results from the recent 2003 National Assessment of Adult Literacy (NAAL) indicate that on a 4-level scale ranging from below-basic to proficient health literacy, only 25 million adults in the United States have proficient health literacy while 75-million adults have health literacy skills at the basic or below basic level (Kutner, Greenberg, Jin, & Paulsen, 2006). Literacy is the ability to read and write or knowledge of a particular subject (Dictionary, 2006). Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (Selden, Zorn, Ratzan, & Parker, 2000)." Achieving proficient health literacy depends upon individual ability, the suitability of the health information from a health literacy perspective, and/or both.

Research in the national population has revealed a link between limited health literacy and disparities in health care utilization and resulting health status. Specifically, limited health literacy is linked to overweight/obesity, higher rates of hospitalization, lower use of preventive services, poorer health status, and higher spending on inpatient and emergency room health care costs (Howard, Gazmararian & Parker 2005). Limited health literacy has been found at higher rates among individuals who are non-Caucasian, have lower education levels and/or income, and may differ by gender (IOM, 2004; Kutner et al., 2006).

In the context of the culture of the military health system (MHS), gender, race, educational level and income should not impact the availability of health services. The degree to which active duty military personnel are able to obtain health information and services needed to make appropriate health decisions, and improve health status is equal. All active-duty personnel have universal access to health care, and yet, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Although the percentage of military personnel classified as ᵔbese (Body Mass Index greater than 30.0) is low compared to the U.S. civilian population (12.4% vs. ↑%), military personnel have shown a steady and statistically significant increase in obesity over the past ₁0 years (up from 8.6% in 2002 to 12.4%) (DoDHA, 2005). Hospitalizations for non battle injuries remain high relative to the Healthy People 2000 objective of 754 injuries per 100,000 ((Total DoD 2635/2679 for 2002/2005 and note that Healthy People 2010 does not specify objective rate and civilian estimates were not reported). Even with universal access to care, rates of overweight/obesity and hospitalization lag behind health improvement goals set in Healthy People 2010 (& 2000 for hospitalizations), and even within a culture that emphasizes health promotion and disease prevention, military personnel do not currently meet health promotion objectives in such areas as blood pressure checks (81.8% vs. 95% objective) and cholesterol checks (57.2% vs. 80% objective).

Limited health literacy may be contributing to disparities in health care utilization and improved health status in active duty military personnel with universal access to health care, services and information. To date, there are no published research studies assessing health literacy in the active-duty military population. Little is known about the degree to which active duty personnel have the capacity to process and understand basic health information, and the subsequent impact of this capacity on health care utilization and improved health status and outcomes. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the national population. The **purpose of this study** is to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of the national population to those of active duty military. The **long-term goal** is to explore the relationship between limited health literacy, health care utilization, and improved health status and outcomes. **It is hypothesized** that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, age, race/ethnicity, and marital status. If such finding(s) are demonstrated, then universal access to ₐre and services within the MHS might not be enough to overcome disparities in health care utilization, ₐealth status, and health outcomes. New policies and targeted patient/health education strategies may need

to be developed and/or implemented to improve health literacy within the active-duty population, before targeted goals for improving health status and increasing use of preventive services can be accomplished.

The **target population** for this study is active-duty military personnel (military personnel) while the **:cessible population** is military personnel who are permanently stationed and/or being treated at Walter Reed Army Medical Center (WRAMC). The **Health Literacy Framework (HLF) will be used to guide this preliminary study.** Within this non-causal framework, literacy is the foundation for health literacy and provides the starting point for understanding and communicating health information and concerns. Health literacy is the bridge or active mediator(s) between military members and health contexts – situations and activities relating to health. The **specific aims of this study** are:

1.   To identify the health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional Health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

2.   To examine the relationship between limited health literacy skills and gender, race/ethnicity, pay grade/rank, age, education level, and marital status in a sample of active-duty military personnel.

3.   To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

The results of this preliminary study are **significant for the Federal government/military** because health literacy research has not been conducted in the active-duty military population although limited health literacy has been identified as a national health problem. This **study is also significant because limited health literacy is related to** poorer health status, lower use of preventive services, and overweight/obesity which in the military can lead to a reduction in individual, unit and operational readiness, e.g., loss duty time, less fit force, as well as increased inpatient health care costs when resources are limited due to wartime pressures.

SECTION B. Background

At least one-third of the population lacks the health literacy skills to effectively use their respective health 'stem. Results from the recent 2003 National Assessment of Adult Literacy (NAAL) indicate that on a 4-level scale ranging from below-basic to proficient health literacy, only 25 million adults in the United States have proficient health literacy while 75-million adults have health literacy skills at the basic or below basic level (Kutner et al., 2006). Literacy is the ability to read and write or knowledge of a particular subject (Dictionary, 2006). Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (Selden et al., 2000)." Achieving proficient health literacy depends upon individual ability, the suitability of the health information from a health literacy perspective, and/or both.

Limited health literacy has been linked to higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited health literacy have also been also been linked to individuals who are non-Caucasian, have a lower education level, and/or income, and may differ by gender (IOM, 2004; Kutner et al., 2006).

In the active-duty military population, the extent of limited health literacy is unknown and no surveys and/or research was found in Cumulative Index to Nursing & Allied Health Literature (CINAHL) and Pubmed databases involving military personnel. The Institute of Medicine (IOM) has however, identified military recruits as a population known to have limited literacy skills and thus, suspected of having limited health literacy skills. Because of this and the concern that other military members may lack proficient health literacy skills, the **IOM has also recommended that DoD develop and support programs that will effectively reduce the negative impact of limited health literacy** and consider exploring ways to make health materials more appropriate and user friendly (IOM, 2004).

The concept of "health literacy" was first identified in a 1974 paper titled Health Education as Social Policy (Selden et al., 2000; Simonds, 1974). In the 1974 paper, Simonds discussed the link between health literacy and health education and called for minimum standards for "health literacy" for all school grade vels. Since that time, the concept of health literacy has been defined in numerous ways with varying ₋mphasis on the skill sets required for health literacy and personal empowerment. The most common definition of health literacy used by the scientific and clinical practice communities is the one developed for

a study by the National Library of Medicine (NLM) literacy to aid in debate over how to define health literacy and advance health literacy programs (Selden et al., 2000). For the NLM study, health literacy was viewed from a skills-based perspective and health literacy was defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Selden et al., 2000). This conceptual definition has been adopted by the IOM and Healthy People 2010 (HHS, 2000) and the majority of the 3500 citations in the NLM bibliography, "Health Literacy," (Selden et al., 2000) and 651 citations in the NLM bibliography "Understanding Health Literacy and its Barriers," (Zorn, Allen, & Horowitz, 2004), rely upon this definition (Tones, 2002).

When the 1992 NALS was conducted, the nationwide survey found that about 90 million U.S. adults (out of 191 million or 47%) could not accurately and consistently locate, match, and integrate information from newspapers, advertisements, or forms (Kirsch et al., 2002). While these adults could perform a variety of straightforward tasks using printed material, they were unlikely to be able to perform, with accuracy and consistency, more challenging tasks using long or dense texts. This means that **in 1992, almost half of the nationwide adult population had basic deficiencies in reading and computational skills or literacy skills that were inadequate for the many tasks needed to function successfully in the economy – including the health care economy** (Parker, 2000). Moreover, of these adults, 40 million were found to be functionally illiterate with the remaining adults having only marginal literacy skills (Parker, 2000). In 2004, Rudd, Kirsch and Yamamoto created a five level health activities literacy scale (HALS) (like the 1992 literacy scale) and re-analyzed the 1992 NALS results with a focus on health related tasks. An estimated 23 million adults were found to perform health-related tasks at the lowest of five levels and 46 percent of adults performed in the bottom two levels (IOM, 2004; Rudd, Kirsch, & Yamamoto, 2004).

Results from the 2003 National Assessment of Adult Literacy (NAAL) which contained the first national assessment of health literacy are consistent with the 1992 NALS results and the Rudd, Kirsch, and Yamamoto (2004) re-analysis. The 2003 NAAL results indicate that on a scale ranging from below basic to proficient health literacy, a majority of the adults in the United States had only intermediate health literacy and 75-million adults had health literacy skills at the basic or below basic level. When these 75+ million adults encounter the health care system, they are likely to have difficulty with routine reading requirements, such as reading prescription bottles, food labels, appointment slips, self-care instructions, and health education brochures (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

Health literacy is now recognized as an important aspect of health promotion and disease prevention and critical to improving the health of our Nation and its citizens. In the military, limited health literacy may be contributing to disparities in health care utilization and improved health status even though active-duty military personnel have universal access to health care, services and information. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the non-military population. The **purpose of this study** is to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of non-military populations to those of active duty military.

Specific Aim 1: To identify the health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

The two most widely accepted instruments for measuring health literacy are the Test of Functional health Literary in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM). The shortened versions of each instrument will be used in this study (S-TOFHLA and REALM (same name), respectively).

The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages for a total of 36 Cloze items (comprehension skills measured). The results are scored on a scale from 1-100 and can be classified in one of three ways: adequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The S-TOFHLA has been shown to have good internal consistency (reliability) (cronbrach's alpha = .68 [4 numeracy items] and .97 [36 Cloze items] for reading comprehension) and

concurrent validity compared to the long version of the TOFHLA (r=.91) and the REALM (r=.80). It takes 8-12 minutes to administer (See Appendix A for copy of S-TOFHLA).

Unlike the S-TOFHLA which measures comprehension (ability to read and understand numbers), the EALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects are asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes by personnel with minimal training and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Appendix B for copy of REALM). The criterion validity for the REALM has been established through correlation with other standardized reading tests at p <0.0001: Pearson Oral Reading Test-Revised (.97); Slosson Oral Reading Test-Revised (.96); and Wide Range Achievement Test (WRAT) reading subtest (WRAT-R) (.88). The REALM has good reliability (test-retest .99) and inter-rater (.99) and as indicated above, is highly correlated with the S-TOFHLA (r=.80). While the S-TOFHLA and REALM have not been used in an active-duty military sample, the instruments have been successfully used in a variety of civilian populations to measure health literacy. Nevertheless, the lack of previous testing in the military and results of the third specific aim should be factors to consider when interpreting the results of this preliminary study.

While the extent of literacy/health literacy has been assessed through the 1992 NALS, 2004 NALS/1992 re-analysis, and the 2003 NAAL (75-million adults with lowest two levels of health literacy skills), these national surveys did not use the TOFHLA or REALM. A review of the literature however, reveals that at least 20 research studies have used the TOFHLA, S-TOFHLA, or REALM to measure the extent of health literacy in civilian populations. These studies show that limited health literacy skills are common with significant variations in prevalence depending upon the setting and population sampled (IOM [2004]; Williams et al [1998]), e.g., racial or ethnic status, general medical, HIV. These studies also suggest that segments of the U.S. population that could be considered at greatest risk for limited health literacy are those that were reported to have higher rates of limited literacy in the 1992 NALS (IOM, [2004]) and 2003 NAAL – minorities and lower income individuals.

As indicated above, health literacy skills have not been measured in the active-duty military population even though segments of the population have been identified by IOM (2004) as at risk for limited health literacy such a military recruits. Based on the sociodemographic characteristics (SDC) used in health literacy research with the national population, other segments of the active-duty military population are also at risk of limited health literacy skills, e.g., non Caucasian, and lower ranking personnel. Hence, it is critically important to asses the extent of health literacy in the active-duty population.

Specific Aim 2: To examine relationship between limited health literacy skills and gender, race/ethnicity, age, pay grade/rank, education level, and marital status in a sample of active-duty military personnel.

In addition to the national literacy/health literacy surveys, studies using the TOFHLA, S-TOFHLA and REALM have reported a link between limited health literacy and gender, higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited health literacy have also been also been linked to SDCs such as being non Caucasian, lower education, and/or lower income (IOM (2004), but as indicated above, non of these linkages have been studied in an active-duty military population.

The SDCs variables of gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) were chosen for this preliminary study because they represent points of comparison between the military and national population (See SDC data collection survey at Appendix C).

As for specific examples in the literature suggesting a link between limited health literacy and the aforementioned variables in the national population, there are several. For example, in a study by (Arnold et al., 2001) involving smoking status, reading level, and knowledge of tobacco effects in low-income pregnant women, there was an association between limited health literacy and race (African American). In ddition, associations between limited health literacy skills and racial and ethnic status have been identified .ı studies involving: HIV/AIDs medication adherence (Kalichman et al., 2000); stage of prostate cancer at diagnosis (Bennett et al., 1998) and (Dewalt, Berkman, Sheridan, Lohr, & Pignone, 2004); mediating effects

of literacy on race; poorer diabetic outcomes (Schillinger et al., 2002) and cervical cancer screening practices (Lindau et al., 2002). A 2003 study found evidence that there were differences in health literacy tatus by race (African and Non-African Americans), but noted that much more research is needed because e results may be due to problems with the instrument or more general issues surrounding the assessment of education (Beers et al., 2003). In any event, the most important observation gleaned from the information presented above is the fact that the demographic groups identified in these studies are the same demographic groups identified as being at risk in the 1992 NALS and the reanalysis by Rudd, Kirsch, and Yamamoto (2004). **However, as noted in the IOM (2004) health literacy report, none of the studies identified in the field of health literacy thus far, have involved a sufficiently large random sample of adults to allow for full extrapolation to other populations.** This preliminary study is an important step in understanding this phenomenon in the context of the active-duty military population.

Additionally, if relationships are found between gender, race/ethnicity, and rank and limited health literacy skills, analysis in this study will progress to the examination of the extent to which gender, race/ethnicity, and rank concepts predict the limited health literacy skills. Health literacy research studies in the national population have demonstrated a relationship between limited health literacy and gender, race/ethnicity, knowledge, health outcomes and socioeconomic status (Bennett et al., 1998; DeWalt, Pignone et al., 2004; IOM, 2004; Kalichman et al., 2000; Lindau et al., 2002).

Specific Aim 3: To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

Like the TOFHLA, the S-TOFHLA was developed and has been used in the national population. To the researcher's knowledge, the S-TOFHLA has not been used in any published military research studies. The TOFHLA was developed in 1993 and found to be a valid, reliable indicator of patient's ability to read health-related materials (Parker, et al., 1995). Construct validity for the original TOFHLA was ensured by using actual hospital medical texts for both the reading comprehension and numeracy subtexts (Nurss, et al, 1995) while concurrent validity was shown by demonstrating statistically significant correlations between the EALM and the Wide Range Achievement Test- Revised (WRAT-R). The WRAT-R is an instrument that nas three subtests which measure the codes which are needed to learn the basic skills of reading, spelling, and arithmetic (IOM, 2004). Correlations of the TOFHLA with the REALM and the WRAT-R were .84 and .74, respectively (p<0.001) by Spearman's rank correlation. The REALM and WRAT-R also have a significant correlation of .88 (Nurss, et al., 1995).

The S-TOFHLA was developed and tested in 1997 in the same setting used for the development and testing of the TOFHLA – in a sample of 238 patient/subjects from an urban public hospital in Atlanta, Georgia. The results of the testing showed good internal consistency as reflected by a cronbach's alpha of .68 for the 4 numeracy items and .97 for the 36 Cloze items in the reading comprehension section. The correlation between the numeracy score and the reading comprehension score was .60 (Baker, et al., 1999; Nurss et al, 1995). The correlation between the S-TOFHLA and the REALM was .80 (Baker, et al., 1999; Nurss et al, 1995). Correlations for subscores of the numeracy and Cloze sections were .61 and .81, respectively. All correlations were significant at p<0.001.

There were however, differences between the S-TOFHLA and the REALM in the mid-range of the tests in that the REALM appeared to overestimate and underestimate subject's reading ability when compared to the S-TOFHLA.. It was suspected that these differences might be due to the fact that some subjects were able to pronounce words correctly, but may still have poor reading comprehension while others may need have difficulty pronouncing words in isolation (without the context of other materials on the S-TOFHLA) (Baker, et al., 1999). In any event, the development and testing of the S-TOFHLA provided a short instruments (8-12 minutes to administer) which can aid in the identification of patients who may require special efforts or new health materials to reach their health care goals. It is important therefore, to evaluate whether the instrument is a reliable, valid, and practical tool, e.g., ease and time of administration, for use in active duty military populations.

SECTION C. Progress/Preliminary Studies

An extensive review of the literature reveals that numerous theories have been used to study the concept of health literacy. Doak, Doak and Root (1996) identified a number of these theories such as the health belief model, trans-theoretical model, social cognitive theory (SCT), and diffusion theory. None of these frameworks however, focus specifically on health literacy. Zarcodoolas, Pleasant, and Greer (2005) recently proposed a multi-dimensional health literacy model which focuses on four central literacy domains; fundamental, science, civic, and cultural. To date, this model has not used to guide published research.

Using the definition of health literacy formulated by the National Library of Medicine and used in Healthy People 2010, the IOM also developed a multi-dimensional health literacy model known simply as the Health Literacy Framework (HLF). The HLF focuses on the three sectors which assume responsibility for health literacy: culture and society, health system, and education system. These sectors provide intervention points for improving an individual's health literacy regardless of an individual's status and/or health system (IOM, 2004). This adaptability makes the HLF ideal for conducting health literacy research in the active-duty military population.

The HLF will be used to guide this preliminary study because as adapted, the HLF represents the theoretical interaction of military members with the three key sectors of health literacy and intervention points: educational systems, health care systems, and cultural/societal factors. Within this non-causal framework, literacy is the foundation for health literacy and provides the starting point for understanding and communicating health information and concerns. Health literacy is the bridge or active mediator(s) between military members and health contexts – situations and activities relating to health. Although associations between health literacy and health outcomes and costs have not been conclusively established, research findings suggest such a strong relationship between the concepts (IOM, 2004). As this is the first study on health literacy within the active-duty military population, this study will focus on the concepts of literacy and health literacy.

A visual depiction of the HLF is provided in Figure 1, below. The diagram shows the essential framework for considering health literacy including the interaction(s) and relationship(s) between the three key sectors and intervention points for improving health literacy skills. Below this diagram, Table 1 sets forth a list of variable names, conceptual definitions, operational definitions, and corresponding measures, contained in the HFL.

Table 1. Health Literacy Framework, Variables, Definitions, and Applicable Measures

Variable Name	Conceptual Definition	Operational Definition	Measure
Literacy	Constellation of skills including reading, writing, basic , numeracy, & speech/speech comprehension in specific contexts [prose, document and quantitative] (Kirsch, 2001)	The grade reading level (or reading difficulty level)(literacy skills) -- in the health context, the ability to read at the 10th grade level or above.	- REALM – Grade Level
Health Literacy	Degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions	Subjects ability to read and understand the things they commonly encounter in the health care setting	- S-TOFHLA - overall assessment of health literacy - REALM – decoding measurement of adult literacy in adults
Health Context (HC) & Intervention Points			
HC/IP - Culture & Society	Shared ideas, meanings, and values acquired by individuals as members of society. Includes social determinants of health such as native language, SDCs, along with influences of mass media and the plethora of health information sources available through electronic sources	SDCs - Gender, Marital Status, Race/Ethnicity, and Pay grade/Rank plus health professional status	-Gender -Age -Rank/Pay grade -Race/Ethnicity -Marital Status -Education level -health professional status (MD, RN, medic, Corpsman, etc.) -Financial and structural access to care (MHS) -Deployed personnel -Policies mandating physical fitness

Variable Name	Conceptual Definition	Operational Definition	Measure
HC/IP Health System	Refers to all people performing health related activities including those working in hospitals, clinics, offices, home health care, public health agencies, regulatory agencies, insurers,& accreditation groups	Military Health System – Program materials used in MHS and sample of military members who use MHS	Not being measured
HC/IP Education System	The education system in the United States (K-12), adult education programs and higher education along with formative and continuing education for health professionals	MHS patient education programs and health professional training including military schools	Not being measured
Health Outcomes (& Costs)	Improvements in health status and/or cost savings but varies because contextual to person or health system being analyzed	Overweight/obesity, $$, knowledge of disease, healthy heart practices, and any other health outcome or monetary measurement	Not being measured

SECTION D. Design

The **purpose of this study** is to conduct preliminary steps in testing the **hypothesis** that the health eracy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, and race/ethnicity. Data will be collected at Walter Reed Army Medical Center (WRAMC). The **target population** for this study is active-duty military personnel while the **accessible population** is active-duty military personnel (military personnel) who are permanent staff, visiting, and/or being treated at WARMC. The overall research design for this is study is descriptive **(Burns & Grove, 2005)**. The design will guide the identification and description of reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy skills and gender, rank and race/ethnicity. The design will also provide a platform for evaluating the reliability, validity and practicality of using the S-TOFHLA in a sample of active duty military personnel.

The SDCs used in the second specific aim are based on relationships found in research on health literacy in the national population. The SDCs to be collected are gender, age, race/ethnicity, pay grade/rank, education level, marital status, and to provide context for data analysis, health professional status. The findings generated by this preliminary study will be used to: (1) gain a better understanding of health literacy in the active-duty military population; (2) provide information that may be useful in the development and/or revision of Federal agency/military policies and/or patient education materials, and (3) facilitate the development of hypotheses to guide future health literacy research.

Specific Aim 1: To identify health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

Rationale. Even though the Federal government has noted that improvements in health literacy will improve ᴴealth outcomes, better use of preventive services, and weight management and prevent

ɔesity/overweight in the national population, there are no studies focused on health literacy in the active-ᴶuty military population. The first specific aim of this study is to describe health literacy skills among a sample of military personnel using the two most widely accepted instruments for measuring health literacy skills – S-TOFHLA and REALM. Comparative differences between males and females, White, non-Hispanics, & non-Whites and officers & enlisted will be assessed based on variations in health literacy skills that have been identified in health literacy research and national surveys to date. The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages – (comprehension skills measured) and can be administered in 8-12 minutes. The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The REALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects will be asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Appendix B).

Design and Procedures. A request for exemption from Institutional review board (IRB) review at WRAMC will be filed with the WRAMC, Exempt Protocol Coordinator (Human Use Committee/IRB). The exemption request is predicated on the fact that the research does not involve the collection of identifying information and (1) uses two measures to test health literacy; and (2) provides an opportunity for subjects to learn about the concept of health literacy regardless of whether subjects choose to participate in the study.

If an exemption is not allowed, the proposal will be filed with the Clinical Investigative Committee. Approval will be sought from the USUHS IRB. After obtaining approval to conduct research at WRAMC, recruitment will be carried out by placing pamphlets and posters in the common area and clinics at

ʲRAMC. A sample of the pamphlet and poster are included in the Appendix for review and approval by the ᴶepartment of Clinical Investigation (DCI) Protocol Coordinator. Upon approval, the pamphlet and poster

will be submitted to the Executive Officer of WRAMC hospital for approval of content and placement with WRAMC.

Working under the guidance of the WRAMC principal investigator (PI), COL Richard Riccardi, a room ıll be identified in which subjects can be tested and/or receive information on health literacy. Use of this room will ensure confidentiality, minimize outside distractions, and allow the researcher to provide information to subjects on the concept and importance of health literacy. For individuals agreeing to become subjects, the researcher will explain what the instruments are and how they are used. If written informed consent is required, each subject will be asked to sign a WRAMC approved informed consent form prior to testing. The following SDCs will then be collected along with health professional status: gender, age, marital status, race/ethnicity, and pay grade/rank.

Data will be collected from a convenience sample of military members at a single point in time at WRAMC. Data collection will take approximately 20-25 days based on a testing schedule of 15 subjects per day. Data will be analyzed to assess the extent of health literacy and to measure relationships between a subject's health literacy skill level and gender, race/ethnicity, marital status, and pay grade/rank.

Data will be kept confidential and only viewed by the researcher and USUHS Graduate School of Nursing dissertation committee members. Data results will be coded and entered into a SPSS spreadsheet by the researcher. Results from the analysis will be used to complete doctoral studies and to facilitate the development of hypotheses to guide future health literacy research. Data will be stored according to USUHS rules and may be used in later research. Consistent with the IOM recommendation for DoD, the results may also provide information that may be useful in the development of effective policies and customized programs that address deficiencies in health literacy skills.

Data Analysis. Data will be collected at the nominal, ordinal, and scale level. Univariate statistics (frequency distributions, measures of central tendency, categorical groupings of literacy level, e.g, reading level, marginal health literacy) will be used to describe SCDs, health professional status, and health literacy skills among in active duty military personnel. The S-STOFHLA scores and standard cutoffs will be used to estimate the proportion of the sample with adequate and inadequate functional health literacy skills. Average scores will be compared across demographic subgroups using a two group (male and female) ıdependent) t-test and/or ANOVA. Table 2 provides an overview of the data analysis plan.

To ensure that the sample size is large enough to conduct the analysis proposed for this study and account for attrition, a sample size of 300 subjects is proposed. However, as this is a preliminary study, the power analysis was conducted based on a sample size of 150. With a 150 subjects, a two group t-test with a .05 two-sided significance level will have .80 power to detect a difference of 11.5 points on the S-TOFHLA when the sample sizes in the two groups are 30 and 120 respectively, assuming the standard deviation of S-TOFHLA scores is 20. This sample size will yield a margin of error of 7.3 percentage points for estimating the prevalence of "inadequate" health literacy skills, assuming a .95, 2-sided confidence interval and a prevalence of .30. The computations will be conducted using SPSS. As indicated above, the S-TOFHLA and REALM have not been used in an active-duty military sample, but have been successfully used i to measure health literacy in the national population. Nevertheless, the lack of testing in the military and results from the third specific aim should be factors to consider when interpreting the results of this preliminary study.

Problems and Solutions. It is estimated that the length of time required for each participant to complete the SDC data sheet, S-TOFHLA and REALM will be 20 minutes (8-12 minutes – S-TOFHLA/2-3 minutes - REALM, respectively). This time period may be too long for some military members to focus on the materials. The solution would be to drop the REALM for those subjects since the S-TOFHLA is the primary health literacy measurement and measures comprehension skills versus decoding skills by the REALM. The loss to the study would be inability to obtain reading grade level for that individual and a smaller sample size to evaluate the reliability, and validity of the S-TOFHLA.

Specific Aim 2: To examine the relationship between health literacy skills and gender, pay grade/rank, age, race/ethnicity, and education level in a sample of active duty personnel.

ationale. In addition to the national literacy/health literacy surveys, studies using the TOFHLA, S-TOFHLA and REALM have reported a link between limited health literacy and gender, higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient

health care costs. Higher rates of limited health literacy have also been linked to SDCs such as being non Caucasian, lower education, and/or lower income (IOM (2004), but as indicated above, none of these ¨nkages (correlations and predictive relationships) have been studied in an active-duty military population.

The SDCs variables of gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) were chosen for this preliminary study because they represent points of comparison between the military and national population (See SDC data collection survey at Appendix C). The rationale and instruments used to measure health literacy skills are the same as for the first specific aim.

Design and Data Analysis. Data will be collected as indicated above and at the nominal, ordinal and scale level. Pearson's product moment correlation will be used to explore the strength of the relationship between two continuous variables such as the S-TOFHLA and REALM, and S-TOFHLA and age in years. Multiple linear regression will be used to describe joint relationships where the dependent variable is the S-TOFHLA score as continuous variable and the independent variables are the SDCs. Categorical independent variables will be dummy coded for inclusion in the multiple linear regression model if relationships suggest performing predictive analysis. Independent samples Chi square will also be used to examine relationships between health literacy skills and categorical variables -- gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) and predictive analysis will be conducted using logistic regression as appropriate.

Problems and Solutions. Same as indicated above in the first specific aim.

Table 2. Variables, Measures (Level of Data), and Analytic Approach

Variable Name	Nominal	Ordinal	Scale	Specific Aim(s) and Analytic Approach
Health Literacy	S-TOFHLA - Adequate & Inadequate (Marginal & Inadequate Combined using S-TOFHLA REALM -Adequate & Inadequate (Reading level <9th grade)	S-TOFHLA – 3 groupings -Inadequate -Marginal -Adequate REALM – 4 groupings -3rd and below -4th – 6th -7th – 8th -9th and above	S-TOFHLA -Score range = 1-100 REALM -Score range = 1-66	Aim 1 -Univariate statistics = measures of tendency, frequency distributions, categorical groupings of S-TOFHLA a REALM -Independent samples t test, ANOVA Chi Square for comparing groups -Mann-Whitney, Phi & Fisher's Exact if appropriate for data to compare groups Aim 2 -Pearson's product moment correlatic Spearman's rank order correlation, an Chi Square to assess relationships Between SDCs (independent Variables (IVs) and test(s) (dependen Variables (DVs)) -Multiple linear regression and logistic regression, as appropriate Aim 3 -Cronbach's Alpha, Pearson's produc Moment correlation, and Spearman's rank order correlation to assess reliability and validity of S-TOFHLA a REALM, respectively.
Sociodemographi Characteristics	Marital status ---Single, never married ---Married, living together ---Separated ---Widowed	Education -Did not graduate from high school -GED certificate -High School Diploma -Some college, but not	Age in years	Aim 1 -Univariate/Descriptive statistics -As IVs, the SDCs will be used to run independent samp t tests and ANOVAs with S-TOFHLA REALM (as DVs) to compare groupin

Variable Name	Nominal	Ordinal	Scale	Specific Aim(s) and Analytic Approach
		4-year college degree or higer		Aim 2 Same as Aim 2, above

SPECIFIC AIM 3. To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of ctive-duty military personnel.

Rationale. Health literacy skills have not been studied in the active-duty military population. The S-TOFHLA will be used to conduct this study along with the REALM. To assess whether the S-TOFHLA is an appropriate instrument for measuring health literacy skills in the military, the reliability, validity, and practicality of the instrument will be evaluated based on the data collected.

Design and Data Analysis. The instruments used to measure health literacy are the same as the previous two specific aims. Cronbach's Alpha will be used to assess reliability (internal consistency) of the S-TOFHLA on the numeracy and Cloze items and a correlation between the two sections determined. Then, the correlation between the REALM and the total scores for the S-TOFHLA, the total score for the numeracy items and the total score for the Cloze items will be assessed with the Pearson's product moment correlation. Spearman rank correlation coefficient will also be used to compare the three S-TOFHLA categories and the four categories of the REALM.

Problems and Solutions. Same as indicated above in the first specific aim.

Ethical Considerations

Inclusion and Exclusion Criteria

The criteria for inclusion in this study are all active-duty military personnel with the exception of those members who suffer from visual impairment such as blindness, speech impairment, are unable to give consent, or otherwise have a physical impairment that would preclude participation. Visual acuity will be determined using a pocket vision screener but will not be recorded (Rosenbaum, Graham-Field Surgical Co., Inc. New Hyde Park, NY). Subjects with vision worse than 20/100 will be excluded unless corrected to ¬t least 20/100. Those with visual acuity between 20/70 and 20/100 will be given a large print (14 font) ₃rsion of the S-TOFHLA. These impediments will be assessed through the interview process by the researcher. In addition, speech impairment will be assessed by researcher when discussing participation in the study with potential subject and blindness by observation of potential subject and questioning as to visual acuity – can they read letters of first word in REALM correctly.

Human Subject Concerns – Informed Consent and Protections

Before any questioning or testing occurs, participants will be required to provide verbal and written informed consent (unless the research is exempted by WRAMC). Participants will also be advised that they can withdraw at any time during the study. Although information regarding demographic characteristics will be obtained, this study the researcher will not ask for or maintain any identifying record(s) or information. Hence, concerns over confidentiality will be minimized with the resulting hope that participants will feel freer to answer questions and test their level of functional health literacy. The researcher will answer any questions posed by subjects regarding the study and will reinforce that participation is voluntary—will use a non-coercive disclaimer. There are no foreseeable risks associated with this study. Prior to collecting data, IRB approval will be obtained from USU and WRAMC.

SECTION E. References

Arnold, C. L., Davis, T. C., Berkel, H. J., Jackson, R. H., Nandy, I., & London, S. (2001). Smoking status, reading level, and knowledge of tobacco effects among low-income pregnant women. *Prev Med, 32*(4), 313-320.

Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. R. (1999). Development of a brief test to measure functional health literacy. *Patient Educ Couns, 38*(1), 33-42.

Beers, B. B., McDonald, V. J., Quistberg, D. A., Ravenell, K. L., Asch, D. A., & Shea, J. A. (2003). Disparities in Health literacy between African American and non-African

American Primary Care Patients. *Abstract. Journal of General Internal Medicine, 18 (Supplement 1),* 169.

Bennett, C. L., Ferreira, M. R., Davis, T. C., Kaplan, J., Weinberger, M., Kuzel, T., et al. (1998). Relation between literacy, race, and stage of presentation among low-income patients with prostate cancer. *J Clin Oncol, 16*(9), 3101-3104.

Burns, N., & Grove, S. K. (2005). *The practice of nursing research: conduct, critique, and utilization* (5th ed.). St. Louis, MO: Elsevier

Dewalt, D. A., Berkman, N. D., Sheridan, S., Lohr, K. N., & Pignone, M. P. (2004). Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med, 19*(12), 1228-1239.

DeWalt, D. A., Pignone, M., Malone, R., Rawls, C., Kosnar, M. C., George, G., et al. (2004). Development and pilot testing of a disease management program for low literacy patients with heart failure. *Patient Educ Couns, 55*(1), 78-86.

Dictionary. (2006). Dictionary.com. from http://dictionary.reference.com/browse/literacy.

Department of Defense (DoD) Survey of Health Related Behaviors Among Active-Duty Military Personnel (2005). RTI International, Research Triangle Park, N.C.

HHS. (2000). *Healthy People 2010: Understanding and Improving Health.* Retrieved. from http://www.healthypeople.gov/Document/tableofcontents.htm#Volume2.

IOM. (2004). *Health Literacy: A Prescription to End Confusion.* IOM (Institute of Medicine). Washington, D.C.: The National Academies Press.

Kalichman, S. C., Benotsch, E., Suarez, T., Catz, S., Miller, J., & Rompa, D. (2000). Health literacy and health-related knowledge among persons living with HIV/AIDS. *Am J Prev Med, 18*(4), 325-331.

Kirsch, I. S., Jungeblut, A., Jenkins, L., & Kolstad, A. (2002). *Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey (3rd ed).* Washington, D.C.: U.S. Department of Education: National Center for Education Statistics.

Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. (2006). *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy:* U.S. Department of Education, Washington, DC: National Center for Education Statistics

Lindau, S. T., Tomori, C., Lyons, T., Langseth, L., Bennett, C. L., & Garcia, P. (2002). The association of health literacy with cervical cancer prevention knowledge and health behaviors in a multiethnic cohort of women. *Am J Obstet Gynecol, 186*(5), 938-943.

National Literacy Act, (1991).

Parker. (2000). Health literacy: a challenge for American patients and their health care providers. *Health Promot. Int., 15*(4), 277-283.

Ratzan, S. C. (2001). Health literacy: communication for the public good. *Health Promot Int, 16*(2), 207-214.

Rudd, R., Kirsch, I., & Yamamoto, K. (2004). *Literacy and Health in America: Policy Information Report.* Princeton, NJ: Educational Testing Service.

Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., et al. (2002). Association of Health Literacy with Diabetes Outcome. *Jama, 288*(4), 475-482.

Selden, C. R., Zorn, M., Ratzan, S., & Parker, R. M. (2000). *National Library of Medicine Current Bibliographies in Medicine: Health Literacy (NLM Pub. No. CBM 2000-1).* Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health.

Simonds, S. K. (1974). Health Education as Social Policy. *Health Education Monogram 2,* 1-25.

Tones, K. (2002). Health literacy: new wine in old bottles? *Health Educ. Res., 17*(3), 287-290.

Workforce Investment Act, 20 U.S.C. 9201 (1998).

Zarcadoolas, C., Pleasant, A., & Greer, D.S. (2005). Understanding health literacy: an expanded model. Health Promotion International, 20(2).195-203.

Zorn, M., Allen, M. P., & Horowitz, A. M. (2004). *National Library of Medicine Current Bibliographies in Medicine: Understanding Health Literacy and its Barriers (NLM Pub.*

No. CBM 2004-1). Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health

SECTION E.   Appendix
   Appendix A – S-TOFHLA
   Appendix B – REALM
   Appendix C – Sociodemongraphic Characteristics & health professional status

Chapter 4. Proposal Defense

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DISSERTATION PROPOSAL DEFENSE

CAPT Konstantine Keian Weld

24 April 2007

UNIFORMED SERVICES UNIVERSITY
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Title of Study

Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel

"The contribution of health towards victory in modern warfare cannot be exaggerated, for good health is the human stuff of which victory is made"

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RECOGNITION

- Doctoral Committee Members
  - Dr. Sandra Bibb
  - Dr. Diane Padden
  - Dr. Gloria Ramsey

Background - Literacy Defined

- Ability to read parts of the Bible, signing name, or completion of certain education level
- By Congress -- "Ability to read, write, and speak in English, compute, and solve problems, at levels of proficiency necessary to function on the job, in the family of the individual, and in society"
- Affirms critical link between literacy and ability to become self-sufficient and participate fully in American life

Background –
Health Literacy Defined

- Has been defined a number of ways
- This proposal uses --

  "Degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions"

- Achieving proficient health literacy depends upon individual ability, the suitability of health information and/or both.

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American Medical Association Foundation and American Medical Association. Help your patient understand. Available at ://www.vdh.state.va.us/epi/pdf/MaySeminar/Health_Director_Sessions/Health_Literacy.pdf

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The Problem

From Rex Morgan M.D. by Woody Wilson & Graham Nolan. Taken from Lurie, N. (2003). Rand: Health Literacy: What is it and What are the Implications for Minnesota's Native American Community, http://www.med.und.nodak.edu/depts/rural/nrcnaa/pdf/lurie.pdf.

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The Problem

- 75+ million - 1/3 of the U.S. population lack the health literacy skills to effectively use their health system - ½ U.S. Population may be at risk
- Link between limited health literacy and disparities in health care utilization and resulting health status
  - Overweight/obesity
  - Higher rates of hospitalizations
  - Lower use of preventative serves
  - Poorer health status
  - Higher spending on inpatient and emergency room costs
- Limited health literacy has been found at higher rates among females, individuals who are non-Caucasion, have lower education levels, and/or lower income

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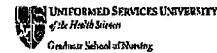
Federal/Military Relevance

- In the context/culture of MHS, gender, race, ed. level, and income should not impact availability of health services
- Ability to obtain health information and services needed to make appropriate health decisions, and improve health status is equal.
- All personnel have universal access to health care. Yet disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes
- Culture that emphasizes health promotion/disease prevention, but don't currently meet health promotion objectives in such areas as BP checks

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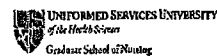
Federal/Military Relevance

- Limited health literacy may be contributing to disparities in health care utilization and improved health status in active-duty military personnel with universal access to health care, services, and information
- To date, there are no published research studies assessing health literacy in the active-duty military population
- Little is known about the degree to which active-duty military personnel have the capacity to process and understand basic health information, and the subsequent impact of this capacity on health care utilization and improved health status and outcomes

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Purpose of Study

- Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in military, research is needed to determine health literacy rates and the comparability of rates to health literacy rates in the national population
- **Purpose** – To determine health literacy rates in active-duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of the national population to those of the active-duty military

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Long Term Goal & Hypothesis

- **Long Term Goal** – To explore the relationship between limited health literacy, health care utilization, and improved health status and outcomes
- **Central Hypothesis** – The health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay, age, race/ethnicity, educational level, and marital status

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Hypothesis - Criticality

- If finding(s) are demonstrated, then universal access to care and services within the MHS might not be enough to overcome disparities in health care utilization, health status, and health outcomes
- New policies and targeted patient/health education strategies may need to be developed and/or implemented to improve health literacy within the military, before targeted goals for improving health status and increasing preventive services can be accomplished

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Specific Aims

In a sample of active-duty military personnel -
- To identify the reading grade level (literacy skills) and health literacy skills using the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Short Test of Functional Health Literacy in Adults (S-TOFHLA)
- To examine the relationship between limited health literacy skills and gender, income as represented by rank/pay, age, race/ethnicity, educational level, and marital status
- To evaluate the reliability, validity, and practicality of the S-TOFHLA

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Significance of the Study

- Health literacy research in military population has not been conducted even though the Federal government and national health organizations have identified limited health literacy as a national health problem
- Limited health literacy is related to poorer health status, lower use of preventative services, higher rates of hospitalizations, and overweight/obesity

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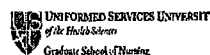
Health Literacy Framework

- Focus of study is on literacy and health literacy
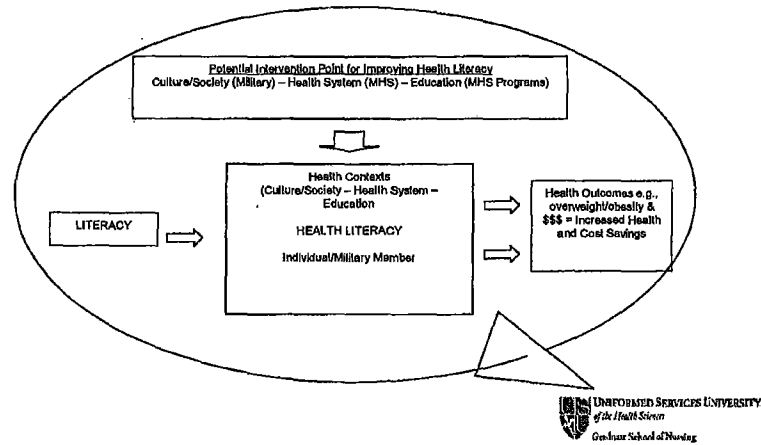
Design

- <u>Descriptive Study Design</u> - Will guide the identification and description of literacy and health literacy skills among military personnel and the examination between health literacy skills and gender, rank, and race/ethnicity
- <u>Target Population</u> – Active-duty military personnel
- <u>Accessible Population</u> – Personnel who are permanent staff and/or being treated or visiting Walter Reed Army Medical Center (WRAMC)

Sociodemographic Characteristics (SDC)

- Gender: Male and Female
- Age in years
- Marital Status:
- Current pay grade/Rank
- Highest level of education
- Race/Ethnicity
- Health Professional Training Status

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Instruments

- S-TOFHLS – Measures an individual's ability to read and understand actual health texts (Comprehension)
  - Consists of 4 numeracy items and 2 prose passages for total of 36 Cloze items)
  - Scored on scale from 1-100 and can be classified in one of three ways – inadequate (0-53), marginal (54-66), adequate (67-100)
  - Administered in 8+ minutes
- REALM – Medical-word recognition test (decoding skills) for adults in medical settings
  - Read from list of 66 common medical terms
  - Each correct pronunciation = 1 point and can be converted into 4 reading grade levels – 0-3, 4-6, 7-8, 9 and above
  - Administered 2+ minutes

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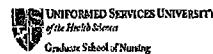
Sample Size

- Sample size – Propose 300; but analysis based on 150 subjects because a preliminary study
- With 150 subjects, a two group t-test with a .05 two-sided significance level will have .80 power to detect a difference of 11.5 points on the S-TOFHLA when sample sizes are 30 and 120, assuming SD is 20
- This sample size will yield a margin of error of 7.3 percentage points for estimating the prevalence of inadequate health literacy skills, assuming a .95, 2-sided confidence interval and a prevalence of .30

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Subjects/Procedures

- Convenience sample obtained at WRAMC
- All active-duty personnel except those who suffer from visual impairment, speech impairment, or are unable to give consent
- After informed consent obtained, SDCs collected
- S-TOFHLA and REALM administered

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Data Analysis

Specific Aim 1 – To identify the reading grade level (literacy skills) and health literacy skills using the REALM and the S-TOFHLA in a sample of active-duty military population

•Nominal, ordinal, and scale level data collected. Univariate statistics used to describe SDC, health professional status, and health literacy skills

•S-TOFHLA scores and standard cutoffs will be used to estimate the proportion of the same with adequate and inadequate functional health literacy skills

•Average scores will be compared across SDC subgroups using a 2-group independent test and/or ANOVA

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Data Analysis

Specific Aim 2 - To examine the relationship between limited health literacy skills and gender, race/ethnicity, age, ed. level, and pay grade/rank in a sample of active-duty military population

•Pearson's product moment correlation will be used to explore the strength of the relationship between two continuous variables such as S-TOFHLA and age in years or one continuous and one dichotomous variable

•Spearman's rank order correlation for ordinal varibles

•Multiple linear regression will be used to describe joint relationships where the dependent variable is the S-TOFHLA score as continuous variable and the independent variables are the SDCs

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Data Analysis

Specific Aim 2 Continued - To examine the relationship between limited health literacy skills and gender, race/ethnicity, age, education level, and pay grade/rank in a sample of active-duty military population

•Categorical IVs will be dummy coded for inclusion in the multiple linear regression model if the relationships suggest doing predictive analysis

•Independent samples Chi square will also be used to examine relationships between health literacy skills and categorical variables and predictive analysis will be conducted using logistic regression, as appropriate

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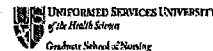
Data Analysis

Specific Aim 3 - To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military population

•Cronbach's Alpha will be used to assess reliability (internal consistency)

•Correlation between S-TOFHLA and REALM by

- Pearson's product moment correlation
- Spearman's rank order correlation

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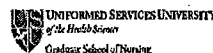
Dissertation Timeline

- 22 April 2007 – Proposal Defense
- IRB – May-July 2007
- Funding – Ongoing
- Study – August – January 2007
  - Recruitment of Subjects - 20-25 days based on testing schedule of 15 subjects per day for both the S-TOFHLA and REALM
  - Data collection, entry and analysis
- Dissemination – Ongoing
- Dissertation Defense – May 2008

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Thanks

- Committee Members
- Drs. Walker, Elberson, and all professors and students
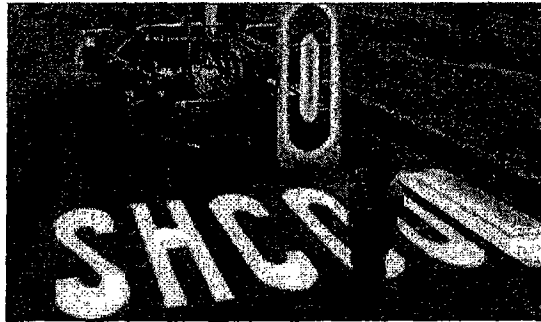
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Almost at End

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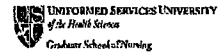
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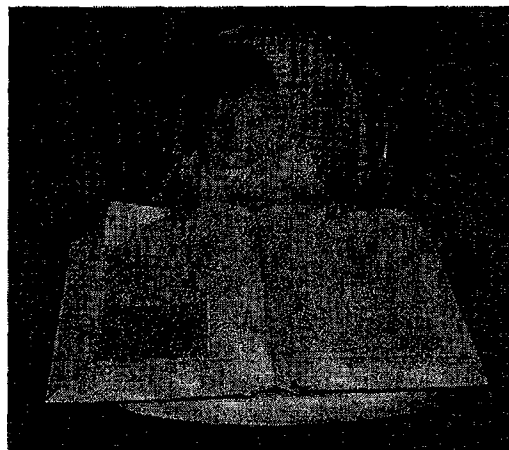
IAmerican Medical Association Foundation and American Medical Association. Help your patient understand. Available at :Iiwww.vdh.state.va.us/epr/pdf/MaySeminar/Health_Director_Sessions/Health_Literacy.pdf

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Uniformed Services University of the Health Sciences
Graduate School of Nursing
Report of Proposal Defense Examination
for the Doctor of Philosophy Degree (Form E)

The proposal defense of___CAPT Konstantine Keian Weld_____,

entitled: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel
was held on 24 April 2007 from _1300_____ to _1400_____. The decision of the Examining
Committee is:

PASS

A. Both the proposal and the oral explanation are satisfactory: _____

B. Minor changes are recommended by the Dissertation Advisory Committee and are to be made *Recruitment and Data Collect*
to the satisfaction of the Dissertation Chairperson: _SCB_ *Recruitment and, procedures*

DEFER

A. Major changes in the proposal are required. Changes must be made to the satisfaction of the
Dissertation Chairperson: _____

B. Major changes are required. Changes must be made to the satisfaction of the Dissertation
Advisory Committee: _____

C. Remediation required prior to making major changes. Completion of remediation must meet
the satisfaction of the Dissertation Advisory Committee: _____

FAIL

Neither the oral performance nor the proposal is adequate: _____

Signatures of the Committee

Chairperson: _Sandra C. B_____

Member: _Diane Padden_____

Member: _Gloris Ramsey_____

Approval/Disapproval

Signature: _Karen Elberson_____   Date: _4/24/07_
          Karen Elberson, RN, PhD
          Director, Doctoral Program

Approval/Disapproval

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Chapter 5. Manuscript 2 – State of the Science

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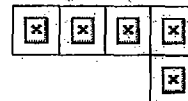
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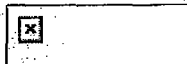
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Title. The evolution and state of an emerging science: Health literacy

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Abstract

Background. Limited health literacy is linked to unsafe health care and poor health outcomes. Limited Health literacy adversely impacts a patient's ability to make informed decisions and to participate fully in their health care. Yet, the evolution of health literacy from its roots in literacy to a new and emerging field of study conceptually linked to patient empowerment is poorly understood.

Data Sources. Existing publications were reviewed for theoretical and empirical information on health literacy through a search of the Cumulative Index to Nursing and Allied Health Literature (CINAL), Medline (PubMed), Psychinfo, Google and Google Scholar, the U.S. National Library of Medicine/National Institutes of Health Current Bibliographies in Medicine 2004-1, and U.S. government websites and materials.

Aim. The purpose of this article is to examine the evolution and current state of the science of health literacy from its roots in literacy to the present.

Methods. A review of medical, nursing, and public health literature from 1974 until November 2007 was conducted according to guidance provided by Burns and Groves (2005).

Results/Conclusions. Improving health literacy is recognized as a means of empowering patients with resulting improvements in individual health status and patient safety. This recognition is reflected in the definitions of health literacy adopted by the U.S. National

Library of Medicine, the World Health Organization, and Zarcadoolas, Pleasant, and Greer (2006). However, the science of health literacy is relatively new and evolving. Nursing research is needed to assess the prevalence of limited health literacy in various populations and causal pathways.

Keywords. literature review, literacy, health literacy, patient education, empowerment, measurement instruments, nursing

SUMMARY

What is already known about this topic

- Limited health literacy is linked to unsafe health care and poor health outcomes.

- Limited health literacy adversely impacts a patient's ability to make informed decisions and to participate fully in their health care.

What this paper adds

- Provides an understanding of how the field of health literacy evolved from its roots in literacy to a new field of study conceptually linked to patient empowerment.

- Identifies commonly used instruments to measure health literacy skills and selected studies to illustrate the evolution of instrument development and research involving health literacy skills.

- Identifies areas for nurses to engage in future health literacy research.

Introduction

Limited health literacy is linked to unsafe health care, poor outcomes, and the inability to make informed health care decisions (Joint Commission (Commission), 2007; Institute of Medicine (IOM), 2004). Improving health literacy is recognized as a means of empowering patients with resulting enhancements in individual health status and patient safety (Baker et al., 2007; Commission, 2007; IOM, 2004; Nutbeam, 1998a, 1998b, 2000; Speros, 2005; Wang, 2000; Zarcadoolas, Pleasant, & Greer, 2006). However, the conceptual link between empowerment and the evolution of health literacy from its roots in literacy to a field of study is still poorly understood. The purpose of this article is to examine the evolution and current state of the science of health literacy through a review of the literature that incorporates selected definitions of literacy and health literacy and identifies the conceptual linkage between the concepts of health literacy and patient empowerment. Instruments commonly used to measure health literacy skills will also be identified along with selected research studies to illustrate the evolution of instrument development and research involving health literacy skills. A review of medical, nursing, and public health literature from 1974 through November 2007 was conducted following guidelines recommended for conducting a literature review outlined in Burns and Grove (2005). Existing publications located through a search of the Cumulative Index to Nursing and Allied Health Literature (CINAL), Medline (PubMed), Psychinfo, Google and Google Scholar, the U.S. National Library of Medicine/National Institutes of Health Current Bibliographies in Medicine 2004-1, "Understanding health literacy and its Barriers," and U.S. government websites and

materials, were reviewed for theoretical and empirical information on health literacy (Burns & Grove, 2005).

Literacy: The Foundation of Health Literacy

The conceptual foundation of health literacy is literacy and this ancient, multifaceted concept can be traced back to the introduction of written language into human society (Speros, 2005). Over the years, the concept of literacy has been constantly redefined based on societal demands, geographical location, and context, e.g., cultural, quantitative, or computer literacy (E. E. Gordon & Gordon, 2003; IOM, 2004; Kirsch, 2001; Speros, 2005). For example, individuals in colonial America were considered literate if they could read at least parts of the Holy Bible while as recently as 1998, "Quaranic literacy," or the ability to read parts of the Holy Quran, was being used as a positive indicator of literacy in the Islamic Republic of Pakistan (Pakistan, 1998). Literacy has also been defined at various times throughout history as the ability to perform certain basic tasks such as the signing of one's name, the completion of a certain level of education (Kaestle, Moore, Stedman, Tinsley, & Trollinger, 1991), or scoring a particular grade level on a school-based measure of reading achievement (Campbell, Kirsch, & Kolstad, 1992).

From 1879 until 1969, the U.S. Federal government defined literacy for use in the national census as the inability to read and write a simple message in English or other language (Census, 2006; Commerce, 1948, 1959, 1960, 1971). In 1988, the U.S. Congress took renewed interest in the concept of literacy and ordered the U.S. Department of Education to submit a congressional report defining the literacy and measuring the nature and extent of literacy among adults in the Nation. As a result of

this congressional action, literacy was newly defined as "the ability to use printed and written information to function in society, to achieve one's goals, and to develop one's knowledge and potential" (Jenkins & Baldi, 1999). This new definition was used for the 1992 U.S. National Adult Literacy Survey (NALS) and 2003 U.S. National Assessment of Adult Literacy (NAAL).Unlike earlier definitions, the new definition of literacy included a broad range of skills that adults use in performing various tasks associated with work, home, and living in a social environment (Jenkins & Baldi, 1999).

In 1991, the U.S. Congress passed the National Literacy Act and offered another definition of literacy: "the ability to read, write, and speak in English and to compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and develop one's knowledge and potential" ("National Literacy Act," 1991). While similar to the definition used in the national literacy surveys, the congressional definition placed new emphasis on English verbal skills and employability. Nevertheless, the trend of defining literacy in terms of empowerment as reflected in the continued emphasis on individual potential and achievement of one's goal(s) was maintained (Kirsch, Jungeblut, Jenkins, & Kolstad, 2002).

In 1998, the U.S. Congress redefined the concept of literacy in the Workforce Investment Act and demonstrated that literacy is indeed a concept that is context specific. Rather than focusing on the potential of the individual and achievement, the new definition emphasized individual proficiency on the job, in the family, and in society. While more narrow than the 1991 National Literacy Act definition of literacy, this approach to defining literacy was consistent with the legislative goal of establishing a national workforce preparation and employment system to meet the needs of businesses

and individuals who want to further their careers. In contrast, U.S. Department of Health and Human Services (HHS) adopted the 1991 National Literacy Act definition of literacy for use in Healthy People 2010 – issued by HHS as part of its nationwide initiative on health promotion and disease prevent (HHS, 2000). In doing so, HHS reaffirmed the connection between literacy and the achievement of one's goals and development of one's knowledge and potential - personal empowerment, and in the context of health care.

In addition the United States, other governmental entities and non-U.S. based organizations have sought to define the concept of literacy with varying emphasis on the connection between literacy and empowerment. For example, Greece, Paraguay, Hungary, Slovakia, and Belize define literacy in terms of school attainment (by increasing levels of attainment) whereas Angola, Chad, Sierra Leone, Sudan, Rwanda, and Zambia define literacy and illiteracy as the ability read a letter or newspaper easily or with difficulty (UNESCO, 2007b). Similarly, in 1958 the United Nations Educational, Scientific, and Cultural Organization (UNESC) defined literacy as "the ability of an individual to read and write with understanding a simple short statement related to his/her everyday life" (UNESCO, 2007a). UNESCO has since taken a more expansive approach to literacy and now views literacy as a skills-based concept consisting of multiple skill domains such as reading and numeracy (UNESCO, 2007a, 2007b). Likewise, the United Nations Children Fund (UNICEF) has also adopted a skills-based definition of literacy (UNESCO, 2007b).

The Center for Literacy of Quebec, Canada, (Center) which is affiliated through the Health Literacy Project with McGuill University Health Center, takes a more

expansive view of literacy. The Center's definition of literacy emphasizes not only context specific skills necessary to function in society, but also literacy's essential role in lifetime learning and consideration as human right (Literacy, 2007). Literacy is also seen as critical to an individual's capacity to use and make critical judgments about the information they encounter on a daily basis such as health information (Literacy, 2007). Thus, like the 1991 National Literacy Act definition used in Healthy People 2010, the Center's definition of literacy affirms the connection between literacy and empowerment in a variety of settings including health care.

Health Literacy: Genesis and Conceptual Development

As the foundation for health literacy, literacy is the cornerstone for being able to make critical judgments and participate fully in one's health care (HHS, 2000; IOM, 2004; Nutbeam, 1998a). Over the last four decades literacy has evolved into a concept linked to empowerment; and health literacy has emerged as a distinct concept linked to patient empowerment, and new field of scientific study.

The term health literacy was first used in 1974 in a paper titled "Health Education as Social Policy (Selden, Zorn, Ratzan, & Parker, 2000; Simonds, 1974). In the paper, Simonds proposed minimum health literacy standards for all school grade levels and emphasized the link between health literacy and health education. However, as Selden et al. (2000) point out, health literacy is not just a problem with the education system. As patients assume more responsibility for their own health care, the problems associated with limited health literacy worsen (Selden et al., 2000). Thus, in making this observation Selden et al. (2000) highlighted the fact that health literacy is a concept with origins in both the health care and education arenas.

The field of health literacy has evolved over the last four decades from two expert groups (Zarcadoolas, Pleasant and Greer (2006). The first group, health care providers and health educators, are focused on patient comprehension and compliance in response to concerns over poor health literacy levels of patients in the American health care system (Kickbusch, 2001; Zarcadoolas et al., 2006). This group has traditionally viewed health literacy as a skills-based concept in which improvements to limited health literacy are driven by a desire to change one's behavior and effectuated through top-down training and skills development – usually by lecture or dialogue (Wang, 2000). This group of health providers and educators, particularly physicians, has also been a critical source of health literacy studies and instrument development (Zarcadoolas et al., 2006). The second group are individuals trained in adult basic education (Zarcadoolas, Pleasant, & Greer, 2005; Zarcadoolas et al., 2006) or adult learning in the Freirean model, particularly as linked to personal empowerment (Kickbusch, 2001). Of these educators, those advocating a Freirean model have been effective in facilitating the incorporation of empowerment into the definition of health literacy and the use of a bottom-up or participatory approach to improving health literacy skills (Kickbusch, 2001; Wang, 2000). Research for this group has focused on interventions to increase literacy skills and health literacy skills through the infusion of health information in curriculum for adult learners (Zarcadoolas et al., 2006).

The conceptual development of health literacy reflects the ideas and involvement of both groups from which health literacy has evolved. For example, the American Medical Association (AMA) Ad Hoc Committee on Health literacy on Scientific Affairs defined health literacy as "a constellation of skills, including the ability to perform basic

reading and numerical tasks required to function in the health care environment (AMA, 1999; Kickbusch, 2001). This definition is clearly skills-based and infers that adequate health literacy means being able to apply literacy skills to health related materials such as medicine labels and prescriptions (Nutbeam, 2000). As a result, the definition is somewhat narrow and misses the deeper meaning of health literacy for most people which is which is that being health literate means being able to more fully participate in one's health decisions, i.e., patient empowerment (Literacy, ; Nutbeam, 2000).

A more progressive definition was developed by the National Library of Medicine (NLM) and adopted by Healthy People 2010 and the IOM. The NLM defined health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (HHS, 2000; IOM, 2004; Ratzan & Parker, 2000)." This definition builds upon the AMA's skills-based approach by identifying the link between adequate health literacy skills and individual potential (IOM, 2004). Thus, the NLM affirmed the conceptual link between health literacy and empowerment previously identified by the World Health Organization (WHO) in 1998. This WHO definition of health literacy is advocated for by followers of Freirean oriented adult education (Kickbusch, 2001; Nutbeam, 1998a, 1998c, 2000; Wang, 2000).

Recently, Zarcadoolas, Pleasant, and Greer (2006) defined health literacy as "the wide range of skills and competencies that people develop over their lifetime to seek out and comprehend, evaluate, and use health information and concepts to make informed choices, reduce health risks, and increase quality of life." Consistent with the WHO and NLM definitions, this definition clearly articulates the connection between health literacy

skills and an individual's ability to participate fully in one's health decisions. Moreover, according to Zarcadoolas, Pleasant, and Greer (2006), patients empowered through better health literacy skills are able to "use health concepts and information generatively, applying information to novel situations" in a participatory manner (Wang, 2000; Zarcadoolas et al., 2005; Zarcadoolas et al., 2006). Thus, Zarcadoolas, Pleasant, and Greer (2006) have put forth a progressive vision of health literacy that acknowledges both the importance of functional skills and the relationship of such skills to the ability of patients to improve not only their health, but life – true patient empowerment.

Health Literacy: The State of an Emerging Science

Measurement Instruments

Parallel to the conceptual evolution of health literacy, the science of health literacy has evolved from reliance on literacy surveys and studies to produce new knowledge to instruments which measure the concept of health literacy (Berkman et al., 2004; IOM, 2004). An example of using a literacy survey is the 1992 the National Adult Literacy Survey (NALS) in the United States which assessed the ability of individuals to use print materials to accomplish tasks (IOM, 2004; Kirsch et al., 2002). In addition to assessing literacy, survey results were also used to estimate the prevalence of limited health literacy in the United States – 90 million or 1/3 of American adults (IOM, 2004; Kirsch et al., 2002). Since the late 1980s, the United States and other industrial nations have continued to use surveys to focus on functional literacy and numeracy skills consistent with the 1991 National Literacy Act definition of literacy (IOM, 2004).

This approach to focusing on functional literacy and numeracy skills was recently seen in the 2003 National Assessment of Adult Literacy (NAAL) in the United States

which was also designed to provide a first large scale measure of health literacy as defined in Healthy People 2010 (Kutner, Greenberg, Jin, & Paulsen, 2006; NAAL, 2007). The results of the NAAL were consistent with the NALS and found that over 75-million adults had basic or below basic health literacy and a least 190 million adults have less than proficient health literacy. Of those surveyed, women scored slightly higher than men, adults over 65 years of age had lower average health literacy skills than adults in lower age groups, and adults with insurance coverage had higher literacy skills than those who were not covered (Kutner et al., 2006; Rudd, 2007).

Since the early to mid-1990s, researchers have used three primary instruments to measure health literacy skills: the Wide Range Achievement Test - Revised (WRAT-R), Rapid Estimate of Adult Literacy in Medicine (REALM), and the Test of Functional Health Literacy (TOFHLA) (Berkman et al., 2004; IOM, 2004). Of these, only the TOFHLA and REALM, or their shortened versions, have a health care/medical focus and are the measurements instruments almost exclusively used in health literacy research (Table 1). The WRAT-R and the REALM are both word recognition tests and measure decoding skills by having them read aloud from a list of words (T. C. Davis et al., 1991; Terry C. Davis et al., 1993; Jastak & Wilkinson, 1984). The reported correlation between the REALM and WRAT-R is r =.88 (Terry C. Davis et al., 1993). In contrast, the TOFHLA measures the concept of health literacy by assessing reading comprehension through a Cloze procedure and numeracy or quantitative literacy (R. M. Parker, D. W. Baker, M. V. Williams, & J. Nurss, 1995a). The TOFHLA is also highly correlated with the REALM and WRAT-R at r=.84 and r-.74, respectively.

Recently, a new quick assessment for health literacy has been developed called the Newest Vita 1 Sign (NVS) (Osborn et al., 2007; Weiss et al., 2005) (See Table 1). The NVS is a 6-item literacy assessment of an individual's ability to read and understand the information on a nutrition label (Osborn et al., 2007). In recent testing, the NVS had a moderate correlation with the REALM (r=.41) and slightly better correlation with the shortened TOFHLA (S-TOFHLA) of r-.61. The investigators in this study noted that while the NVS may be useful in as a clinical screening tool, research may require a more precise tool. In addition, versions of the TOFHLA for adolescents and Hebrew speaking individuals have also been developed as well as a REALM version for teenagers. Initial testing indicates these instruments are valid and should be available for nurse researchers (Baron-Epel, Balin, Daniely, & Eidelman, 2007; Chisolm & Buchanan, 2007; Terry C. Davis et al., 2006)

Research Studies: Prevalence, Relationships, and Interventions

The focus of research in the emerging field of health literacy has been in three areas: (1) the prevalence of limited health literacy in various populations (Berkman et al., 2004; IOM, 2004; Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005); (2), the relationship between health literacy and outcomes (Berkman et al., 2004; Dewalt, Berkman, Sheridan, Lohr, & Pignone, 2004; IOM, 2004); and (3) interventions to improve health outcomes for patients with limited health literacy (Berkman et al., 2004; IOM, 2004; Pignone, DeWalt, Sheridan, Berkman, & Lohr, 2005).

As of January 2004, there were 85 published research studies specifically addressing the prevalence of limited health literacy in various populations (Paasche-Orlow et al., 2005). Since then, researchers have continued to conduct prevalence studies

in a variety of populations such as a sample of British adults (Wagner, Knight, Steptoe, & Wardle, 2007); spinal cord injured patients (Johnston, Diab, Kim, & S., 2005); care givers (Sanders, Thompson, & Wilkinson, 2007); diabetic patients (Morris, MacLean, & Littenberg, 2006); and rheumatoid arthritis patients (Buchbinder, Hall, & Youd, 2006). To illustrate the evolution of prevalence studies using the most common measurement tools for health literacy skills, a selective sample of such studies is listed in Table 2.

Research focusing on health outcomes and interventions has also gained momentum since the emergence of health literacy as a science, but is still quite limited. For example, as of 2004, only 44 published health outcomes studies and 20 intervention studies were identified and of the latter group, only 5 controlled trials stratified their results by literacy level (Berkman et al., 2004; Dewalt et al., 2004; Pignone et al., 2005). Since then, research has also continued in these two areas as illustrated by studies such as: a controlled trial which demonstrated that interventions can empower patients with limited health literacy to discuss prostate cancer and prostate-specific antigen (PSA) test orders with physician (Kripalani et al., 2007); a study that demonstrated the relationship between mortality and limited health literacy among elderly persons (Baker et al., 2007); and a study that established a relationship between limited health literacy and higher health costs among Medicare enrollees (Howard, Gazmararian, & Parker, 2005). To further illustrate the evolution of health outcome and intervention studies, selective study samples are provided in Table 3.

The studies listed in Tables 2 and 3 do not represent the full spectrum of published research studies in health literacy. These studies reflect the evolution of health literacy research to its present state in which researchers continue to conduct prevalence

studies in new populations while exploring opportunities in outcomes and intervention research. In pursing the latter, scholars and researchers are just beginning to grapple with the complex issues of causal pathways between limited health literacy and health outcomes, and the strategies to address inadequacies in health literacy (IOM, 2004; Paasche-Orlow & Wolf, 2007; Wolf, Davis, & Parker, 2007).

Conclusion and Identified Areas for Future Nursing Research

Limited health literacy is a major public health concern. Improving health literacy is recognized as a means of empowering patients with resulting improvements in individual health status and patient safety (IOM, 2004; Kripalani et al., 2007). This recognition is reflected in the definitions of health literacy adopted by the NLM, WHO, and Zarcadoolas, Pleasant, and Greer (2006) and in a recent study by Kripalani et al. (2007).

However, the science of health literacy is also relatively new and evolving. The extent of limited health literacy in various populations is still unknown and an area in need of further nursing research. In particular, health literacy research is needed in populations with health disparities such as non-Caucasians and the elderly (Carmona, 2003a, 2003b; IOM, 2004). Moreover, nursing research is also need to explore the issue of causal pathways between limited health literacy and health outcomes which are as yet unknown. Finally, research leading to the development of strategies and interventions to improve health literacy is still in its infancy and clearly needed. Since professional nurses have traditionally assumed a key role in patient education, nurses researchers are in an ideal position to spearhead research in this area.

References

AMA. (1999). Ad Hoc Committee on Health Literacy for the American Council on Scientific Affairs. Health Literacy: Report of the Council on Scientific Affairs. *Journal of American Medical Association, 281*, 552-557.

Arnold, C. L., Davis, T. C., Berkel, H. J., Jackson, R. H., Nandy, I., & London, S. (2001). Smoking status, reading level, and knowledge of tobacco effects among low-income pregnant women. *Prev Med, 32*(4), 313-320.

Baker, D. W., Parker, R. M., Williams, M. V., & Clark, W. S. (1998). Health literacy and the risk of hospital admission. *J Gen Intern Med, 13*(12), 791-798.

Baker, D. W., Parker, R. M., Williams, M. V., Clark, W. S., & Nurss, J. (1997). The relationship of patient reading ability to self-reported health and use of health services. *Am J Public Health, 87*(6), 1027-1030.

Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. R. (1999). Development of a brief test to measure functional health literacy. *Patient Educ Couns, 38*(1), 33-42.

Baker, D. W., Wolf, M. S., Feinglass, J., Thompson, J. A., Gazmararian, J. A., & Huang, J. (2007). Health Literacy and Mortality Among Elderly Persons. *Arch Intern Med, 167*(14), 1503-1509.

Baron-Epel, O., Balin, L., Daniely, Z., & Eidelman, S. (2007). Validation of a Hebrew health literacy test. *Patient Education and Counseling, 67*(1-2), 235-239.

Bass, P. F., 3rd, Wilson, J. F., & Griffith, C. H. (2003). A shortened instrument for literacy screening. *J Gen Intern Med, 18*(12), 1036-1038.

Berkman, N. D., DeWalt, D. A., Pignone, M. P., Sheridan, S. L., Lohr, K. N., Lux, L., et al. (2004). *LIteracy and health outcomes. Agency for Healthcare Research and Quality. Evidence Report/Technology Assessment No. 87, (Prepared by RTI International-University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016). AHRQ Publication No. 04-E007-2. Rockville, MD: January 2004.* .

Buchbinder, R., Hall, S., & Youd, J. M. (2006). Functional health literacy of patients with rheumatoid arthritis attending a community-based rheumatology practice. *J Rheumatol, 33*(5: 879-886).

Burns, N., & Grove, S. K. (2005). *The practice of nursing research: conduct, critique, and utilization* (5th ed.). St. Louis, MO: Elsevier

Busselman, K. M., & Holcomb, C. A. (1994). Reading skill and comprehension of the dietary guidelines by WIC participants. *J Am Diet Assoc, 94*(6), 622-625.

Campbell, A., Kirsch, I. S., & Kolstad, A. (1992). *Assessing Literacy: The Framework for the National Adult Literacy Survey.* U.S. Department of Education. Washington, DC: National Center for Education Statistics.

Carmona, R. H. (2003a, April 27, 2004). Keynote Speech for National Managed Health Care Congress Summit: Reducing Racial and Cultural Disparities in Health Care: What Actions Now? , from http://www.surgeongeneral.gov/news/speeches/managedcare031103.htm

Carmona, R. H. (2003b). Speech on September 19, 2003 to Pfizer Sixth National Health Literacy Conference: Health Literacy: Key to improving America's Health. from http://www.surgeongeneral.gov/news/speeches/healthlit09192003.htm

Census. (2006). *Population Characteristics from STF3 Appendix B, Definitions of Subject Characteristics.* Retrieved. from www.census.gov/geo/lv4help/apen_bpop.html.

Chisolm, D. J., & Buchanan, L. (2007). Measuring Adolescent Functional Health Literacy: A Pilot Validation of the Test of Functional Health Literacy in Adults. *Journal of Adolescent Health, 41*(3), 312-314.

Commerce. (1948). *Illiteracy in the United States: October 1947.* Retrieved. from http://www.census.gov/population/www/socdemo/past-educ.html.

Commerce. (1959). *Estimates of Illiteracy by States 1950.* Retrieved. from http://www.census.gov/population/www/socdemo/past-educ.html.

Commerce. (1960). *Literacy and Educational Attainment: March 1959.* Retrieved. from http://www.census.gov/population/www/socdemo/past-educ.html.

Commerce. (1971). *Illiteracy in the United States November 1969.* Retrieved. from http://www.census.gov/population/www/socdemo/past-educ.html.

Commission. (2007). *Report by the Joint Commission. What Did the Doctor Say?:Improving Health Literacy toProtect Patient Safety.* Attention: Director of Public Affairs: One Renaissance Boulevard, Oakbrook Terrace, Illinois 60181.

DAV. Instrument summary for health literacy. U.S. Department of Veterans Affairs (DAV). Office of Research and Development Health Services Research & Development Service (HSR&D). from http://www.hsrd.research.va.gov/for_researchers/measurement/instrument/overvie ws/is_literacy.cfm#wrat-r

Davis, T. C., Crouch, M. A., Long, S. W., Jackson, R. H., Bates, P., George, R. B., et al. (1991). Rapid assessment of literacy levels of adult primary care patients. *Fam Med, 23*(6), 433-435.

Davis, T. C., Fredrickson, D. D., Arnold, C., Murphy, P. W., Herbst, M., & Bocchini, J. A. (1998). A polio immunization pamphlet with increased appeal and simplified language does not improve comprehension to an acceptable level. *Patient Education and Counseling, 33*(1), 25-37.

Davis, T. C., Long, S. W., Jackson, R. H., Mayeaux, E. J., George, R. B., Murphy, P. W., et al. (1993). Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Fam Med, 25*(6), 391-395.

Davis, T. C., & Mayeaux, E. J. (1994). Reading ability of parents compared with reading level of pediatric patient education materials. *Pediatrics, 93*(3), 460.

Davis, T. C., Wolf, M. S., Arnold, C. L., Byrd, R. S., Long, S. W., Springer, T., et al. (2006). Development and Validation of the Rapid Estimate of Adolescent Literacy in Medicine (REALM-Teen): A Tool to Screen Adolescents for Below-Grade Reading in Health Care Settings. *Pediatrics, 118*(6), e1707-1714.

Dewalt, D. A., Berkman, N. D., Sheridan, S., Lohr, K. N., & Pignone, M. P. (2004). Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med, 19*(12), 1228-1239.

Donelle, L., Hoffman-Goetz, L., & Arocha, J. F. (2007). Assessing health numeracy among community-dwelling older adults. *J Health Commun, 12*(7), 651-665.

Gazmararian, J. A., Baker, D. W., Williams, M. V., Parker, R. M., Scott, T. L., Green, D. C., et al. (1999). Health literacy among Medicare enrollees in a managed care organization. *Jama, 281*(6), 545-551.

Gazmararian, J. A., Parker, R. M., & Baker, D. W. (1999). Reading skills and family planning knowledge and practices in a low-income managed-care population. *Obstet Gynecol, 93*(2), 239-244.

Gazmararian, J. A., Williams, M. V., Peel, J., & Baker, D. W. (2003). Health literacy and knowledge of chronic disease. *Patient Educ Couns, 51*(3), 267-275.

Gordon, E. E., & Gordon, E. H. (2003). *Literacy in America: Historic Journey and Contemporary Solutions.* Westport, CT: Praeger.

Gordon, M. M., Hampson, R., Capell, H. A., & Madhok, R. (2002). Illiteracy in rheumatoid arthritis patients as determined by the Rapid Estimate of Adult Literacy in Medicine (REALM) score. *Rheumatology (Oxford), 41*(7), 750-754.

Griffin, J. M. (2007). Determining the Prevalence of Health Literacy Among Veterans: Funding Period January 2004 - September 2006. No Publications at this time. . from http://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141693695 &UnderReview=no

HHS. (2000). *Healthy People 2010: Objectives for improving health (Part A: focus areas 1-14)* Retrieved. from http://www.healthypeople.gov/Document/pdf/Volume1/11HealthCom.pdf.

Howard, D. H., Gazmararian, J., & Parker, R. M. (2005). The impact of low health literacy on the medical costs of Medicare managed care enrollees. *Am J Med, 118*(4), 371-377.

IOM. (2004). *Health Literacy: A Prescription to End Confusion (Bohlman, L.N., Panzer, A.M., Kind, D.A., eds).* Institute of Medicine of the National Academies:Washington, D.C.: The National Academies Press.

Jastak, S. R., & Wilkinson, G. S. (1984). *Wide range achievement test-revised.* Wilmington, DE: Jastak Associates. .

Jenkins, L., & Baldi, S. (1999). *National Adult Literacy Survey: An Overview (Chapter 1). Retrieved.* U.S. Department of Education. Washington, DC: National Center for Education Statistics and Division of Adult Education and Literacy.

Johnston, M. V., Diab, M. E., Kim, S. S., & S., S. K. (2005). Health literacy, morbidity, and quality of life among individuals with spinal cord injury.. *J Spinal Cord Med, 28*(3).

Kaestle, C. F., Moore, H. D., Stedman, L. C., Tinsley, K., & Trollinger, W. V. (1991). *Studying the history of literacy (by Kaestle, C.F.). In Literacy in the United States: Readers and Reading Since 1880.* New Haven: Yale University Press.

Kalichman, S. C., Benotsch, E., Suarez, T., Catz, S., Miller, J., & Rompa, D. (2000). Health literacy and health-related knowledge among persons living with HIV/AIDS. *Am J Prev Med, 18*(4), 325-331.

Kalichman, S. C., Ramachandran, B., & Catz, S. (1999). Adherence to combination antiretroviral therapies in HIV patients of low health literacy. *J Gen Intern Med, 14*(5), 267-273.

Kalichman, S. C., & Rompa, D. (2000). Functional health literacy is associated with health status and health-related knowledge in people living with HIV-AIDS. *J Acquir Immune Defic Syndr, 25*(4), 337-344.

Kickbusch, I. S. (2001). Health literacy: addressing the health and education divide. *Health Promot. Int., 16*(3), 289-297.

Kirsch, I. S. (2001). The framework used in developing and interpreting the International Adult Literacy Survey. *European Journal of Psychology and Education, 16*(3), 335-361.

Kirsch, I. S., Jungeblut, A., Jenkins, L., & Kolstad, A. (2002). *Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey (3rd ed)*. Washington, D.C.: U.S. Department of Education: National Center for Education Statistics.

Kripalani, S., Sharma, J., Justice, E., Justice, J., Spiker, C., Laufman, L. E., et al. (2007). Low-Literacy Interventions to Promote Discussion of Prostate Cancer: A Randomized Controlled Trial. *American Journal of Preventive Medicine, 33*(2), 83-90.

Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. (2006). *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. U.S. Department of Education. Washington, DC: National Center for Education Statistics.

Literacy. (2007). Definition of Literacy. Centre of Literacy. Montreal, Quebec. *The Centre for Literacy*, from http://www.centreforliteracy.qc.ca/def.htm

Morris, N. S., MacLean, C. D., & Littenberg, B. (2006). Literacy and health outcomes: a cross-sectional study in 1002 adults with diabetes *BMC Fam Pract. , 7*(49).

Murphy, P. W., Chesson, A. L., Walker, L., Arnold, C. L., & Chesson, L. M. (2000). Comparing the Effectiveness of Video and Written Material for Improving Knowledge Among Sleep Disorders Clinic Patients With Limited Literacy Skills(*). *Southern Medical Journal, 93*(3), 297.

NAAL. (2007). National Assessment of Adult Literacy (NAAL): Health Literacy - Development and Administration. from http://nces.ed.gov/naal/health_dev.asp

National Literacy Act, (1991).

Nutbeam, D. (1998a). Health promotion glossary. *Health Promot. Int., 13*(4), 349-364.

Nutbeam, D. (1998b). *World Health Organization: Health Promotion Glossary*. Geneva.

Nutbeam, D. (1998c). World Health Organization: Health Promotion Glossary.

Nutbeam, D. (2000). Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot. Int., 15*(3), 259-267.

Osborn, C. Y., Weiss, B. D., Davis, T. C., Skripkauskas, S., Rodrigue, C., Bass Iii, P. F., et al. (2007). Measuring Adult Literacy in Health Care: Performance of the Newest Vital Sign. *American Journal of Health Behavior, 31*, S36-S46.

Paasche-Orlow, M. K., Parker, R. M., Gazmararian, J. A., Nielsen-Bohlman, L. T., & Rudd, R. R. (2005). The Prevalence of Limited Health Literacy. *JGIM: Journal of General Internal Medicine, 20*(2), 175-184.

Paasche-Orlow, M. K., & Wolf, M. S. (2007). The Causal Pathways Linking Health Literacy to Health Outcomes. *American Journal of Health Behavior, 31*, S19-S26.

Pakistan. (1998). Prime Minister's Literacy Commission: Adult Literacy in Pakistan: Quaranic Literacy Project. One of the papers were presented at the Second Asia Regional Literacy Forum-Innovation and Professionalization in Adult Literacy: A Focus on Diversity, New Delhi, India, February 9-13, 1998., from

Parker, R. M., Baker, D. W., Williams, M. V., & Nurss, J. (1995a). The Test of Functional Health Literacy in Adults (TOFLA): A new instrument for measuring patient's literacy skills. *Journal of General Internal Medicine, 10*, 537-542.

Parker, R. M., Baker, D. W., Williams, M. V., & Nurss, J. R. (1995b). The test of functional health literacy in adults: a new instrument for measuring patients' literacy skills. *J Gen Intern Med, 10*(10), 537-541.

Pignone, M., DeWalt, D. A., Sheridan, S., Berkman, N., & Lohr, K. N. (2005). Interventions to Improve Health Outcomes for Patients with Low Literacy. A Systematic Review. *Journal of General Internal Medicine, 20*(2), 185-192.

Ratzan, S. C., & Parker, R. M. (2000). *Introduction. In: National Library Medicine Current Bibliographies in Medicine: Health literacy: January 1990 through 1999. Selden, C.R., Zorn, M., Ratzan, S.C. & Parker, , R.M., Editors. NLM Pub. No. CBM 2000-1. Bethesda, M.D.: National Institutes of Health, U.S. Department of Health and Human Services.* .

Rudd, R. E. (2007). Health Literacy Skills of U.S. Adults. *American Journal of Health Behavior, 31*, S8-S18.

Sanders, L. M., Thompson, V. T., & Wilkinson, J. D. (2007). Caregiver Health Literacy and the Use of Child Health Services. *Pediatrics, 119*(1), e86-92.

Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., et al. (2002). Association of health literacy with diabetes outcomes. *Jama, 288*(4), 475-482.

Scott, T. L., Gazmararian, J. A., Williams, M. V., & Baker, D. W. (2002). Health literacy and preventive health care use among Medicare enrollees in a managed care organization. *Med Care, 40*(5), 395-404.

Selden, C. R., Zorn, M., Ratzan, S., & Parker, R. M. (2000). *National Library of Medicine Current Bibliographies in Medicine: Health Literacy (NLM Pub. No. CBM 2000-1).* Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health.

Simonds, S. K. (1974). Health Education as Social Policy. *Health Education Monogram 2*, 1-25.

Speros, C. (2005). Health literacy: concept analysis. *Journal of Advanced Nursing, 50*(6), 633-640.

UNESCO. (2007a). United Nations Educational, Scientific and Cultural Organization: Glossary (Education for All Global Monitoring Report). from http://portal.unesco.org/education/en/ev.php-URL_ID=43385&URL_DO=DO_TOPIC&URL_SECTION=201.html

UNESCO. (2007b). United Nations Educational, Scientific and Cultural Organization: Literacy for life: Chapter 6. Understandings of literacy from http://portal.unesco.org/education/en/ev.php-URL_ID=43283&URL_DO=DO_TOPIC&URL_SECTION=201.html

Wagner, C. v., Knight, K., Steptoe, A., & Wardle, J. (2007). Functional health literacy and health-promoting behaviour in a national sample of British adults. *J Epidemiol Community Health, 61*(12), 1086-1090.

Wang, R. (2000). Critical health literacy: a case study from China in schistosomiasis control. *Health Promot. Int., 15*(3), 269-274.

Weiss, B. D., Mays, M. Z., Martz, W., Castro, K. M., DeWalt, D. A., Pignone, M. P., et al. (2005). Quick assessment of literacy in primary care: the newest vital sign. *Ann Fam Med, 3*(6), 514-522.

Williams, M. V., Parker, R. M., Baker, D. W., Parikh, N. S., Pitkin, K., Coates, W. C., et al. (1995). Inadequate Functional Health Literacy Among Patients at Two Public Hospitals. *Jama, 274*(21), 1677-1682.

Wolf, M. S., Davis, T. C., & Parker, R. M. (2007). Editorial: The Emerging Field of Health Literacy Research. *American Journal of Health Behavior, 31*, S3-S5.

Zarcadoolas, C., Pleasant, A., & Greer, D. S. (2005). Understanding health literacy: an expanded model. *Health Promot. Int., 20*(2), 195-203.

Zarcadoolas, C., Pleasant, A. F., & Greer, D. S. (2006). *Advancing health litearcy: A framework for understanding and action.* San Francisco: CA: Jossey-Bass.

Zun, L. S., Sadoun, T., & Downey, L. (2006). English-language competency of self-declared English-speaking Hispanic patients using written tests of health literacy. *J Natl Med Assoc, 98*(6), 912-917.

Table 1:. Instruments commonly used in health literacy research

Instrument	Description	Type of Score
TOFHLA (Spanish, Hebrew and teen versions available)	1. Tests reading comprehension as measured by Cloze procedure and numerical ability 2. Measures patients' ability to read and understand health-related materials commonly used in health-care settings 3. Full TOFHLA takes about 22 minutes and shortened version (S-TOFHLA) takes 10-12 minutes to complete 67 items Citations: (Baker, Williams, Parker, Gazmararian, & Nurss, 1999; DAV, ; R. M. Parker, D. W. Baker, M. V. Williams, & J. R. Nurss, 1995b)	1. Continuous Score 2. Three categories of functional health literacy: adequate, marginal, and inadequate
REALM (Spanish and teen versions available)	1. Medical word recognition and pronunciation 2. Designed to be used in public health and primary care settings to identify patients with low reading levels. 2. Original REALM takes 3-5 minutes to administer and the shortened version 1-2 minutes by personnel with minimal training. 3. The shortened version (66 words) is the most widely used and an even shorter 8-item version, the REALM – Revised, has been developed as a health literacy screening tool. Citations: (Berkman et al., 2004; DAV, ;	1. Continuous Score 2. Estimated reading grade level below 9th grade (4 Categories)

Instrument	Description	Type of Score
	T. C. Davis et al., 1991; Terry C. Davis et al., 1993; IOM, 2004; Jastak & Wilkinson, 1984)	
WRAT-R	1. Word recognition and pronunciation 2. Commonly used in educational settings, but the reading subscale has been used in the medical field to measure literacy in health care 3. Takes between 10-20 minutes to administer (57-item test requiring pronunciation of letters and words0 Citations: (Bass, Wilson, & Griffith, 2003; Berkman et al., 2004; DAV, ; IOM, 2004; Jastak & Wilkinson, 1984)	1. Continuous Score 2. Estimated educational grade level
NVS	1. 6-item literacy assessment of an individual's ability to read and understand the information on a nutrition label (Osborn et al., 2007; Weiss et al., 2005) 2.	1. Continuous Score of 0-6 which equates to categories (0-1 = limited literacy; 2-3 = limited literacy; possible; and 4-6 = adequate literacy

Note: Table 1 lists the three primary instruments used to measure health skills: the Wide Range Achievement Test - Revised (WRAT-R), Rapid Estimate of Adult Literacy in Medicine (REALM), and the Test of Functional Health Literacy (TOFHLA) (Berkman et al., 2004; IOM, 2004), and a recently developed quick assessment instrument for measuring health literacy in patients; Newest Vital Sign (NVS) (Osborn et al., 2007; Weiss et al., 2005). The first column identifies the measurement instrument. The second column describes what type of skill-set each instrument is designed to measure and contains basic administration information along with references used in the article. The third column of the table provides the type of scores or variables that each instrument can be studies by nurse researchers.

Table 2. Selected Health Literacy Prevalence Studies

Citation	Sample Population & Setting (studies for instrument development are noted)	Measurement Instrument
(T. C. Davis et al., 1991)	1. Adults 2. Six public and private primary care clinics Note. Instrument development study for original REALM	1. REALM 2. WRAT-R 3. Slosson Oral Reading Test-Revised (SORT-R).
(Terry C. Davis et al., 1993)	1. Adults in four university hospital clinics (internal medicine, family practice, ambulatory care, and obstetrics/gynecology) and state prisoners to determine test-retest reliability Note. Instrument development study for shortened REALM	1. REALM (shortened version) 2. WRAT-R 3. Peabody Individual Achievement Test – Revised (PIAT-R) 4. SORT-R
(Busselman & Holcomb, 1994)	1. Women - WIC enrollees and non-enrollees 2. WIC Supplemental Food Program – Study focus on reading skills and comprehension of 1990 Dietary Guidelines in WIC program (literacy in health area)	1. WRAT-R
(Terry C. Davis & Mayeaux, 1994)	1. Parents or other caretakers accompanying pediatric outpatients 2. Pediatrics outpatient clinic in a large, public university, teaching hospital.	1. REALM 2. WRAT-R
(Parker et al., 1995b)	1. Adults (English and Spanish speaking) 2. Outpatient settings in two public teaching hospitals Note. Instrument development for	1. TOFHLA 2. REALM 3. WRAT-R

Citation	Sample Population & Setting (studies for instrument development are noted)	Measurement Instrument
	TOFHLA	
(Williams et al., 1995)	1. Predominantly indigent and minority patients, (English and Spanish speaking) 2. Two urban, public hospitals	1. TOFHLA
(Baker et al., 1999)	1. Adults 2. Urgent care cent at an urban public hospital – Same site used to develop TOFHLA	1. S-TOFHLA 2. REALM
(Gazmararian, Baker et al., 1999)	1. Elderly patients/Medicare enrollees (English and Spanish speaking) 2. Multi-state national managed care organization – Prudential, .	1. S-TOFHLA
(Gazmararian, Parker, & Baker, 1999)	1. Women 2. Medicaid managed care plan – Prudential in Tennessee	1. TOFHLA (abbreviated version)
(Kalichman et al., 2000)	1. Adults – Men and Women who were HIVpositive 2. AIDS service organizations and HIV clinics	1. TOFHLA
(Schillinger et al., 2002)	1. English and Spanish speaking adults over 30 years old with type 2 diabetes. 2. Two primary care clinics affiliated with public hospital	1. S-TOFHLA
(Bass et al., 2003)	1. Adults -18-93 years old; 85% white 2. Internal medicine clinic of varying educational levels and income Note. Instrument development focus on shorter REALM – Result as 8-item	1. REALM-R 2. WRAT-R

Citation	Sample Population & Setting (studies for instrument development are noted)	Measurement Instrument
	REALM screening devise	
(Weiss et al., 2005)	1. Adult 2. Primary care patients Note. Study to develop quick screening test for limited literacy in English and Spanish	1. Newest Vital Sign (NVS) 2. TOFHLA
Johnston et al., 2005	1. 107 community-living patients with spinal cord injury (SCI) in New Jersey, U.S.A. outpatient SCI center	1. TOFHLA
(Terry C. Davis et al., 2006)	1. Schools and primary care/pediatric clinic 2. Adolescents -50% black and 53% female; 34% were enrolled in middle school and 66% in high school. Note. Instrument development focus for using REALM in adolescent populations	1. REALM-Teen 2. WRAT-R 3. SORT-R
(Zun, Sadoun, & Downey, 2006)	1. English speaking Hispanic adults 2. Urban level-1 pediatric and adult trauma center	1. REALM 2. S-TOFHLA
(Morris et al., 2006)	1. English speaking adults with diabetes	1. S-TOFHLA
(Buchbinder et al., 2006)	1. Patients with rheumatoid arthritis (RA) attending community-based rheumatology practice.	1. TOFHLA 2. REALM 3. Test of Reading Comprehension (TORCH)
(Osborn et al., 2007)	1. Adults 2. Public clinics Note. Continued instrument development	1. NVS 2.REALM 3. S-TOFHLA

Citation	Sample Population & Setting (studies for instrument development are noted)	Measurement Instrument
	of NVS	
(Donelle, Hoffman-Goetz, & Arocha, 2007)	1. Senior Aduls (men and women over 50 years old) 2. Non-clinical setting	1. STOFHLA (assessing numeracy skills)
(Griffin, 2007)	1. Adults. 50-75 year old veterans in four VA Medical Centers	1. S-TOFHLA
(Wagner et al., 2007)	1. British adults (men and women) excluding Northern Ireland and Scottish Isles	1.TOFHLA
(Sanders et al., 2007)	1. Caregivers from caregiver-child dyads from sample f children aged 12 months to 12 years 1. Pediatric emergency department of urban public hospital	1. S-TOFHLA

Note. To illustrate the evolution of health literacy prevalence studies, Table 2 provides a selective sample of such studies using the most common measurement tools for health literacy skills. The first column lists the study title and citation reference. The second column provides a listing of the sample population that was studied and the research setting in which the study took place. The third column lists the measurement instruments used to assess health literacy skills in each study.

Table 3. Selected Health Outcomes and Intervention Studies

Citation	Health Literacy Association with outcome or noted as intervention study	Measurement Instrument
(Baker, Parker, Williams, Clark, & Nurss, 1997)	Self-reported health and use of health services	TOFHLA
(Terry C. Davis et al., 1998)	Intervention study – Comparison of two polio pamphlets on patient comprehension	REALM
(Baker, Parker, Williams, & Clark, 1998)	Risk of hospitalization	TOFHLA
(Kalichman, Ramachandran, & Catz, 1999)	Predictors of adherence to treatment for HIV and AIDS	TOFHLA
(Kalichman & Rompa, 2000)	Health status, AIDS-related disease and treatment knowledge, and health care perceptions and experiences	TOHFLA
(Murphy, Chesson, Walker, Arnold, & Chesson, 2000)	Intervention study – compare effectiveness of video and written material for improving knowledge among patients with sleep disorders with limited health literacy	REALM and structured questionnaire
(Arnold et al., 2001)	Reading level, tobacco knowledge, attitudes, and practices of tobacco use among pregnant adult and adolescent women	REALM
(M. M. Gordon, Hampson, Capell, & Madhok, 2002)	Impact of illiteracy on disease severity and function.	REALM
(Scott, Gazmararian, Williams, & Baker, 2002)	Preventive health care among Medicare enrollees	S-TOFHLA
(Gazmararian, Williams, Peel, & Baker, 2003)	Knowledge of disease among patients with a chronic disease	S-TOFHLA
(Howard et al., 2005)	Medical care use and costs	S-TOFHLA
(Baker et al., 2007)	Mortality among Medicare enrollees	S-TOFHLA

Citation	Health Literacy Association with outcome or noted as intervention study	Measurement Instrument
(Kripalani et al., 2007)	Intervention study - controlled trial with low health literacy patients demonstrated patients were empowered to discuss prostate cancer and prostate-specific antigen (PSA) test orders with physician	REALM and patient education handout on prostate screening, a handout simply encouraging patients to talk to their doctor about prostate cancer (Cue), or a control handout.

Note. To illustrate the evolution of health outcome and intervention studies in the field of health literacy, Table 3 provides a selective study sample of such studies using the most common measurement instruments for health literacy skills. The first column lists the study title and citation reference. The second column provides a listing of the sample population that was studied and the research setting in which the study took place. The third column lists the measurement instruments used to assess health literacy skills in each study.

Chapter 6. Manuscript 3 - Theory

A Framework for Guiding Health Literacy Research in Populations With Universal Access to Healthcare

CPT Konstantine Keian Weld, JD, BSN, LLM; Diane Padden, PhD, CRNP; Gloria Ramsey, JD, RN; Sandra C. Garmon Bibb, DNSc, RN

At least one third of the US population suffers from limited health literacy, which has been linked to poorer health status, higher costs, and individuals who are socioeconomically disadvantaged. However, research and the development of theoretical frameworks to study health literacy have only recently begun to occur. The purpose of this article is to describe theoretical frameworks that have either been used or may be used to guide health literacy research and to identify implications for nursing research and practice related to an adaptation of a health literacy framework developed specifically for conducting research in populations with universal access to healthcare. **Key words:** *health communication, health disparities, health literacy, literacy, microrange theory, military health system, patient education, theoretical framework, universal access*

HEALTH LITERACY is typically defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[1] At least one third of the population lacks the health literacy skills to effectively use their respective health system.[2,3] Furthermore, limited health literacy has been linked to higher rates of hospitalization, lower use of preventive services, poorer health status, and higher costs. It has also been linked to individuals who are nonwhite, have lower education levels, and/or incomes; there may be differences in health literacy rates based on gender.

Research to study health literacy has only recently begun to occur. Health literacy research has been conducted to explore health literacy rates in population groups with varying levels of access to care. However, little is known about health literacy rates and associated outcomes (hospitalization rate, use of preventive services, health status, healthcare costs) in groups where the availability of health services is equal or universal within the group. Universal access to care exists when an identified spectrum of healthcare services are provided with or without cost to individuals through a systematic approach.[4] Universal access creates a culture of equality where only personal or individual preferences limit utilization of health services. Even though personal preferences may impact

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access, equal availability of service creates a culture of universality that may impact health literacy rates and associated outcomes. The purpose of this article is to present a conceptual framework adapted for use in studying health literacy in population groups with universal access to care. As a foundation to the presentation of this adapted framework, a comprehensive overview of conceptual frameworks, which have been used to guide research in the emerging field of health literacy, is also provided. The article also contains a discussion of implications for future health literacy research and clinical nursing practice applications for the adapted framework.

FRAMEWORKS FOR GUIDING HEALTH LITERACY RESEARCH

Research is not a goal in itself, but rather, an instrument to facilitate the advancement of nursing science and the extension of knowledge in general. To achieve these ends, research must either generate or test theory.[5] Research designed to generate theory is concerned with the identification, discovery, or definition of a phenomenon of interest and/or the relationship between aspects of the phenomenon. In contrast, the aim of research designed to test a theory is to produce new science through the development of evidence about hypotheses derived from the tested theory.[6] *Theory* in this case refers to either a conceptual framework composed of concepts and/or theories that were created to guide a particular study or a theoretical framework of concepts that exists in literature and is used to guide research.[7] For nurses interested in health literacy research, numerous theoretical and conceptual frameworks are available in the literature that have been used to guide health literacy research. Several of these frameworks and associated core assumptions are identified in this article along with application examples and issues to be considered when using these frameworks to conduct health literacy research.

EDUCATIONAL AND BEHAVIORAL MODELS

In their groundbreaking book, Doak et al[8] identified several educational and behavioral theories that could be used to guide research and interventions involving literacy in medicine. These theories include the health belief model (HBM), social cognitive theory/self-efficacy (SCT), locus of control theory, cognitive dissonance theory, diffusion theory, transtheoretical model/stages of readiness, and adult education theories two of these theories, the HBM and SCT are also identified by Glanz et al in their seminal work on health behavior and education theories, and both theories have been used to guide health literacy research. However, unlike the frameworks presented later in this article, the HBM and SCT do not focus on the concept of health literacy and have limitations, which nurses should carefully consider before choosing these theories to guide health literacy research.

The HBM focuses on individual or personal health behavior and is among the most widely applied theoretical frameworks for the study of health behavior change. The HBM was developed in the 1950s by social psychologists from the US Public Health Service to explain the widespread failure of individuals to participate in health screening and prevention programs.[9] Since then, the HBM has been widely used to design and evaluate interventions to alter health behaviors such as those involving the relationship between health literacy skills and health screening and to guide analysis of large data sets to understand health behavior.[10]

The primary assumptions of the HBM are that a person will take a health-related action if the person (1) feels a negative health outcome can be avoided; (2) has a positive expectation that by taking a recommended action, a negative health condition can be avoided; and (3) believes that a recommended health action can be successfully taken.[11] In essence, the HBM conceptualizes health behavior as being determined by a person's

awareness of a negative health concern and realization that the concern can be avoided. For example, obesity is a negative health consequence and the desire to avoid obesity can be used to motivate an individual to change his/her behavior. One way to increase this desire is to make obesity and its health consequences more understandable through improved health literacy.[12] Similarly, Davis et al[13] used the HBM to guide their research into the association between inadequate health literacy skills and low rates of colorectal cancer screening. In this study, it was surmised that for individuals to undergo cancer screening, they must realize that they are susceptible to getting cancer, that cancer is a serious disease, and that a positive health action to treat cancer is possible. Although versatile and used in a wide variety of settings, there have been concerns over the use HBM to guide health literacy research. First, the primary focal point of HBM is on the individual so it may not be the most effective framework for studying health programs involving health literacy where the focal point is the program.[8] Moreover, researchers have expressed concerns about inconsistent measurement of the HBM's concepts in both descriptive and intervention research and over the relationship between HBM constructs because ambiguity about the relationships makes testing of construct validity more difficult.[14,15] Finally, of particular concern is the fact that because factors other than health beliefs influence health behavior (eg, culture, previous experience, socioeconomic status), the HBM may not provide the specificity to support health literacy research.[16]

In contrast to the HBM, SCT is an interpersonal theory of health behavior with a core assumption that the interpersonal environment is one of the strongest influences on health-related behavior and health status.[17] Social cognitive theory is a theory of skill and competency management and cognitive behavior control. The theory emphasizes the importance of enhancing a person's behavioral capability (knowledge and skills) and self-confidence (self-efficacy) to engage in a particular health behavior.[18] Unlike the HBM, which is primarily focused on explaining health behavior, the SCT focuses on providing individuals with the knowledge, skill, or self-confidence to adopt positive health behaviors. As a result, SCT is a more appropriate framework than the HBM for guiding health literacy research where the purpose is to not only explain health behavior in relation to health literacy but also to provide interventions to improve an individual's ability to adopt positive health behaviors, for example, adherence to medical regiments, proper exercise, and diet.

Social cognitive theory was developed by Albert Bandura and stems from the social learning theory, which dates back to the late 1800s. The SCT has a number of complex constructs such as reciprocal determinism, environments and situations, observational learning, behavioral capability, reinforcement, outcome expectations, outcome expectancies, and self-efficacy.[17] Indeed, 2 of the concerns most often expressed by researchers about SCT are that the comprehensiveness of the framework's formulation (1) makes the constructs of SCT difficult to operationalize and (2) can be used to explain almost any phenomenon being studied.[17-19] Because of these concerns over complexity, application of the SCT often focuses on 1 or 2 concepts, such as self-efficacy, while ignoring the other concepts of the theory.[17-19]

The purpose of SCT is to understand and predict individual and group behavior and to identify methods in which behavior can be modified or changed. In SCT, *human beings* are defined as a triadic, dynamic, and reciprocal interaction of personal factors, behavior and the environment and their behavior is uniquely determined by each of these factors.[17] While maintaining the notion that response consequences mediate behavior, SCT contends that behavior is largely regulated antecedently through cognitive processes. As a result, response consequences of a behavior are used to form expectations of behavioral outcomes. Furthermore, it is postulated that these

expectations give human beings the capability to predict the outcomes of their behavior, before the behavior is performed, and thus make positive health changes.[17,20,21]

Social cognitive theory has been widely used to study public health problems ranging from prevention of alcohol problems among adolescents between the ages of 11 and 18 years[22] to the promotion of exercise among breast cancer patients.[23] Furthermore, SCT has also been used as the theoretical framework for studies involving health literacy. For example, both the HBM and SCT were used as the theoretical underpinnings in a study to develop customized Web-based education materials that facilitate a parent's active participation in the treatment decisions and care of a child's illness. In this context, SCT/self-efficacy provided the foundation for developing a 12-item assessment of self-efficacy and tailored behavioral health messages.[24] In addition, SCT has also provided the underpinnings for a study that found that although low literacy was a significant risk factor for improper adherence to medical regimens for human immunodeficiency virus, self-efficacy mediated this relationship.[25] Finally, SCT/self-efficacy provided the theoretical underpinnings for a recent health literacy study that examined the relationship between diabetes, self-efficacy, and self-management behavior in an urban, diverse, low-income population with a high prevalence of limited health literacy. In a sample of 408 subjects, Sarkar et al[26] found that the associations between self-efficacy and self-management were consistent across race/ethnicity and health literacy levels

In summary, although the HBM and the SCT can be useful frameworks for guiding health literacy research, careful consideration should be given to each theory's focus and limitations before being chosen to guide research. For example, although versatile and widely used in public health research, serious concerns have been raised over inconsistent measurement of the HBM's concepts. Likewise, the SCT's complexity and focus on self-efficacy may limit a researcher's ability to fully understand the concept of the health lit-

eracy. In contrast, the theoretical frameworks presented in the following section are specifically focused on the concept of health literacy and have been developed concurrently with the scientific evolution of health literacy.

HEALTH LITERACY MODELS

In addition to educational and behavioral models such as the HBM and SCT, 4 conceptual frameworks have recently been introduced, which focus specifically on the concept of health literacy. The development of these frameworks coincides with the evolution of health literacy as a new field of science emerging in the 1990s and the recent national focus on limited health literacy by the Federal government. Instead of focusing on health beliefs or general behavioral influences that may impact an individual's health literacy, the 4 new health literacy frameworks provide specific theoretical guidance on understanding and researching the actual construct of health literacy and on social, environmental, and cultural factors that may explain and even predict health literacy skills in a variety of populations.

For example, Zarcadoolas et al proposed a new multidimensional model (Zarcadoola, Pleasant, and Greer [ZPG] model) for understanding and studying the concept of health literacy. The ZPG's definition of health literacy provides the foundation for the model and although similar to the definition listed in *Healthy People 2010*, it is a more expansive construct. Zarcadoolas et al define *health literacy* as "the wide range of skills and competencies that people develop over their lifetime to seek out, comprehend, evaluate, and use health information and concepts to make informed choices, reduce health risks, and increase quality of life."[27] Using this definition, the ZPG model is built around 4 central domains: (1) *fundamental literacy*, which refers to the ability to read, write, speak, and work with numbers; (2) *scientific literacy*, which refers to the skills and abilities to understand and use science and technology;

(3) *civil literacy*, which refers to skills and abilities that enable citizens to recognize public issues and participate in civil society; and (4) *cultural literacy*, which refers to abilities to recognize, understand, and use the collective beliefs, customs, and worldview, and social identity of diverse individuals to interpret and act on information.[27] Since publication of the ZPG model in 2006, no published research studies that the model as the conceptual/theoretical framework have been identified. The lack of published research studies using the ZPG model may be attributable to both the newness of the model and the complexity of the ZPG model's definitional underpinnings and domains in light of current limitations in measuring health literacy.[28]

In 2004, the Institute of Medicine (IOM) published its report, Health Literacy: A Prescription to End Confusion, and presented a new, noncausal conceptual framework for considering health literacy.[2] The conceptual model simply referred to as "the health literacy framework (HLF)," is an interactive model that places literacy as the foundation of health literacy as defined in *Healthy People 2010*.[2] Health literacy serves as the active mediator between individuals and health contexts, and this active mediation, in turn, impacts individual health outcomes and costs.[2]

In the HLF, individuals bring specific skills sets, abilities and limitations to the health context involving health literacy such as cognitive abilities, social skills, and physical and mental conditions. The 3 key sectors comprising the contexts of health literacy are (1) *culture and society*, which refers to the shared ideas, meanings and values of societal members; (2) *education system*, such as the 12-grade school system and adult education; and (3) *health system*, which is defined as all people performing health activities such as those in hospitals, clinics, public health agencies, and research centers. According to the HLF, it is within these 3 sectors that individual health literacy skills are initially developed and future intervention points for improving health literacy skills can be identified.[2]

Consistent with the ZPG model, published research studies citing the HLF as a theoretical underpinning for the studies have not been identified. The lack of published research studies citing the HLF is not surprising as the science of health literacy is a new and emerging field of study and the HLF is a noncausal model that has only been available for the past 3 years. Indeed, in their 2007 article proposing a new conceptual framework describing causal pathways linking health literacy to health outcomes, Paasche-Orlow and Wolf note that to date, most of the literature on health literacy involves cross-sectional studies, and empirical evidence regarding health literacy and causation is quite limited.[29]

The Paasche-Orlow's and Wolf's model (POW model)[29] is a component-cause conceptual model that is commonly used in epidemiological research and assumes that limitations in health literacy are the result of multiple factors. On the basis of the definition of health literacy used in *Healthy People 2010*, the POW model builds on the HLF to describe the systemic, interactional, and self-care mechanisms by which limited health literacy is most likely to lead to worse health outcomes and higher healthcare costs. Recognizing that limited health literacy is associated with patient-level socioeconomic characteristics such as race/ethnicity, age, and education level, the POW model focuses on the direct pathway that progresses from literacy, through health literacy, to health outcomes and costs. Along this causal pathway, the POW model theorizes that limited health literacy is impacted by 3 major areas, which are further broken down by individual/patient and system or provider-level factors: (1) access and utilization to healthcare; (2) provider-patient interaction such as knowledge, beliefs, and teaching ability; and (3) self-care such as self-efficacy, motivation, and resources.[29]

As a component-cause model, the POW model is thorough, but still incomplete. For example, the POW model does not address several areas of complexity that may be significant in health literacy research. The concept of literacy is also treated as a single, fixed

concept versus a multifaceted concept that may vary over time because of independent conditions involving the patient, such as age or health condition, for example, dementia.[29] Moreover, Passche-Orlow and Wolf point out that the model does not address problems in the field of health literacy that stem from measurement issues similar to the ZPG model and may oversimplify the concept of health literacy, which is multifaceted, but generally viewed in research as being dichotomous. Finally, the POW model may over emphasize the linear pathway from literacy, through health literacy, to health outcomes and costs. Although impossible to avoid, Passche-Orlow and Wolf[29] acknowledge that this concern is really a by-product of the fact that people exist in social relationships and these relationships exert influence on an individual's literacy and health literacy on a continuing basis.

Lastly, Manganello has recently proposed a new conceptual framework that also draws heavily on the HFL and is designed to study and understand adolescent health literacy (AHL model). However, unlike the POW model, the AHL model is based on a more complex definition of health literacy than found in *Healthy People 2010* to connect the pathway between individual characteristics, such as age, race, cognitive skills and media use, and health outcomes and costs. Instead, the AHL model combines the concept of media literacy with Nutbeam's[30] concept of health literacy, which consists of 3 types of health literacy: functional, interactive, and critical. This view of health literacy is similar to the definitional models of health literacy used by the World Health Organization and the ZPG model[31] and therefore, introduces a level of complexity that may not be fully evaluated by the instruments currently available to measure health literacy skills.

Similar to the HFL, the AHL model proposes that family and peer influences and systems such as mass media, education system, and health have a direct impact on health literacy. These factors in turn impact health outcomes, which include health behavior, health costs, and health service use.[31]

Because of the large volumes of health literacy research focusing on health outcomes in adolescents and adolescent health literacy skills in general, Manganello[32] makes several recommendations regarding research in adolescents. First, measurement tools should be designed for use in adolescent populations such as recently developed Rapid Estimate of Literacy in Medicine—Teen. Second, the relationship between individual traits and adolescent health literacy and outcomes should be examined in terms of both association and causation. And finally, interventions need to be developed and evaluated to promote better health literacy skills in adolescents.[31]

UNIVERSAL ACCESS THEORY FOR HEALTH LITERACY SKILLS— MILITARY FOCUS

The IOM has noted that active-duty military personnel may be at risk for limited health literacy, the most vulnerable being military recruits.[2] The IOM has specifically recommended that the Department of Defense develop programs to reduce the negative effects of limited health literacy, such as producing health material for military patients that are clear and written at an appropriate level.[2] Although health literacy has been studied in the veteran population,[33] there are currently no published research studies focusing on the health literacy rates and skills among a sample of active-duty military personnel. To address this disparity, a research study focusing on a sample of active-duty military personnel at a major medical center has been initiated.[18]

The purpose of the study is to determine health literacy rates in active-duty military personnel receiving healthcare and services within a culture of universal access and compare the health literacy rates of the national population to those of active-duty military on the basis of gender, income, and race/ethnicity. As previously mentioned, universal access exists when a spectrum of healthcare services ranging from comprehensive care to primary care or disease specific

care, are provided with or without cost to individuals through a systematic approach such as the military health system (MHS), Medicare and Medicaid, affordable insurance coverage, refundable tax credits, or other health financing approaches.[4] Because there were no theoretical frameworks specifically focused on health literacy research in populations with universal access to healthcare, the general HLF was adapted to guide the research study in the military medical center.[2] The adapted approach or microrange theory is referred to as the universal access theory for health literacy skills (UAT) with military focus.

The rationales for considering the HLF for adaptation were the framework's simplicity, primary focus on health literacy skills, and the fact that the framework's general interactive concepts are easy to adapt for the purposes of guiding health literacy research in a variety of populations, such as active-duty military personnel with universal access through the MHS.[2] For example, consistent with all health literacy frameworks, the concept of literacy is maintained as part of the conceptual foundation of the UAT but operationally defined by using an estimated grade reading level. This approach allows the Rapid Estimate of Adult Learning in Medicine (REALM) to be used among a military population as both a screen to estimate grade reading level and a measure of health literacy skill level. The *REALM* is an instrument that tests decoding skills and takes approximately 2 to 3 minutes to administer.[34]

In the UAT, *health literacy* is also defined conceptually and operationally in accordance with the definition used by the Federal government in *Healthy People 2010* and focuses on an individual's ability to read and understand health information commonly encountered in a healthcare setting. In so doing, the health literacy skills of active-duty military subjects can be measured by both the REALM and Short Test of Functional Health Literacy in Adults (STOFHLA). However, unlike the REALM, the STOFHLA measures functional health literacy skills on the basis of a combined assessment of numeracy and read-

ing comprehension skills. The STOFHLA takes approximately 8 to 12 minutes to administer.

With the foundational concepts of literacy and health literacy in place, the focus of the UAT remains similar to the general HLF and other health literacy frameworks in that health literacy skill level is impacted by individual ability and preferences and the health and/or social environment within which the individual exists. However, in keeping with the purpose of the research in a major military medical center, the primary focus of the adapted model or microrange theory was on the military culture of universal access to care. Of course, this focus does not negate the possible impact of sociodemographic characteristics and noneconomic determinant(s) on health literacy skills. Rather, and although not fully addressed in this article, the relationships between sociodemographic characteristics and influences, military culture, and universal access to care, and the impact of these concepts on health literacy skill level, remain the distinguishing features of UAT model used in this study.

In the military, culture refers not only to the shared ideas, meanings, and values acquired by individuals before joining the military but also to those characteristics acquired as part of the indoctrination and continued orientation into a distinct command and control culture governed by a defined rank structure. Unlike many segments of the general population, military members receive healthcare and services within a culture of universal access available through the MHS. The reason for this all-encompassing approach to healthcare is to ultimately maintain a healthy and fit force (physically and mentally) under the global health concept of force health protection.[35] Although the study focuses on the military culture, within the UAT (and the military itself), the separation between military culture and the MHS are not entirely distinct concepts. Rather, the MHS operates as both an independent concept and as a subset of the military culture in which individual military members operate. Likewise, if the UAT were used to guide a non–active-duty military

population with universal access, the health system offering universal access (eg, health insurance, primary care) would also operate as both an independent influence and as a subset of the circumstances in which patients live.

Civilian training (education) is also a critical influence on health literacy skill level and is composed of the educational programs and activities, which each military member has experienced before joining the military. However, within the MHS, once military members join the service they are provided with mandatory training and classes as well optional educational opportunities that are either provided by their service or paid for by the individual service member. For example, the military currently engages in literacy skills enhancement for its recruits to enable them to function adequately in their respective roles.[2] In addition, the MHS provides no-cost educational opportunities to military members, which can improve their health literacy. Therefore, the concept of training may be an independent concept that influences health literacy skill level, a subset of the MHS or larger military culture, or civilian based education programs, or all of three.

Finally, the concerns over individual health status and costs in the military are similar to those seen in all population groups, with the exception that, the focus of the MHS is ultimately on maintaining a fit and healthy force to defend the Nation. In other words, force health protection is the ultimate health outcome for the military service members. The individual health of military members is not only critical to this mission but also essential for maintenance of family health. Costs are also an important concern, but rather than at an individual level the concern is at a system level (military service or Federal government) because military members exist in a culture of universal access to healthcare. Therefore, within the military structure, the UAT is reflected as 3 interconnecting circles representing the military culture, training/education system, and MHS influencing a military member's literacy and health literacy

skills. The overlapping interconnections of the circles represent the reality that although military members are on duty 24 hours a day, 7 days a week, members are influenced by military culture as well as by their prior civilian status where there might have been variances in access to care and education. These influences impact a military member's literacy and health literacy skills, which impact the military's force readiness and healthcare costs with further implications for the nation's defense. This can be illustrated as an interconnecting circle that provides a unifying bridge between the individual military member, health literacy, force health protection and costs, and national defense (Figure 1).

CONCLUSION: IMPLICATIONS FOR FUTURE RESEARCH AND CLINICAL NURSING PRACTICE

Health literacy research is still in its scientific infancy. However, the need for future health literacy research is essential to identifying nursing practices, which will eliminate health disparities and further the science of nursing.[1] In fact, *Healthy People 2010* has specifically recognized that improving limited health literacy is essential to eliminating health disparities in the national population and the nurse-patient interaction is an important context for improving a patient's health literacy skills.[1] In addition, descriptive studies that have been conducted in a variety of populations indicate that there are variations in health literacy skills on the basis of sociodemographic characteristics, such as racial/ethnic groups and gender,[36] the disease/illness. Nurses will continue to play a vital role in addressing the negative impact of these variations. Thus, it is anticipated that the "HLF, or an adaptation such as" the UAT, will help guide future health literacy research among groups that have not been studied, but that have universal access to healthcare through variety of healthcare systems.

For instance, studies that focus on the association between health literacy skills and

Universal Access Theory for Health Literacy Skills (with military focus)*
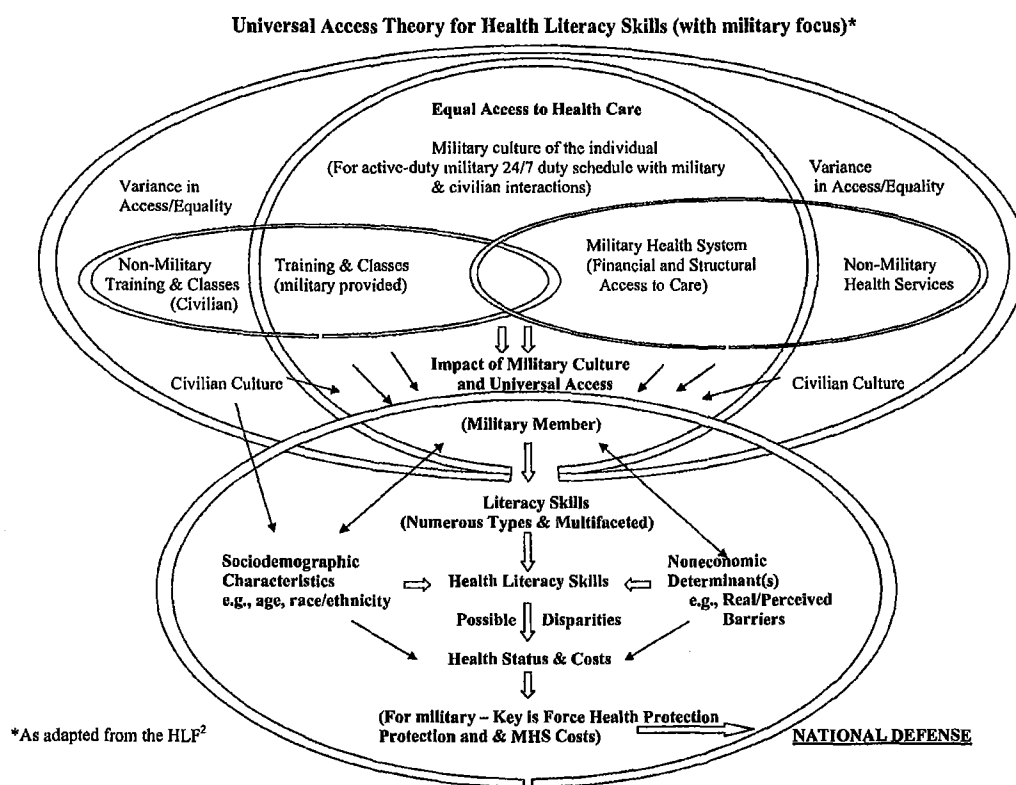
Figure 1. Universal access theory for health literacy skills (with military focus). Reprinted with permission from Institute of Medicine.[2]

health outcomes among active-duty military members within a culture of universal access are needed to better understand the impact of limited health literacy on various aspects of health, such as (1) use of healthcare services, for example, immunizations;[37] (2) health outcomes and costs;[38] (3) disparities in outcomes or healthcare services among traditionally disadvantaged individuals in the active-duty population;[38] and (4) identification of noneconomic determinant(s) that may negatively impact health literacy. Research of these associations between health literacy skills and health outcomes are critical for the military as improvements in health literacy skills may lead to improvements in overall force health protection and a decrease in MHS costs. More importantly, correlational research may help identify patients who may

need additional patient education and/or discharge planning to facilitate their care and optimize their health outcome(s), which parenthetically applies to all patients regardless of the health system in which the patient operates. Ultimately, correlational research could lead to changes in healthcare policy and patient education materials as well as identify future areas of research that will have a positive impact on force health protection, including patient care and costs.

In addition to descriptive and correlational research, health literacy research in populations with universal access is also needed to better understand the causal pathways between health literacy skills and health outcomes. Research examining causal pathways is not only lacking but also critical to furthering the science of health literacy in

a number of areas including, but not limited to, access and utilization of healthcare services, provider-patient interaction, and self-care.[29,37] Moreover, once an empirical understanding of causal pathways is established, nurse researchers will then be able to engage in intervention research for the purpose of mitigating limited health literacy. Although intervention research is less common than association or causal pathway research, intervention research is essential for the development of nursing strategies to mitigate the effects of limited health literacy and improvement of health outcomes.
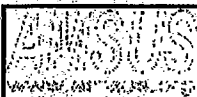
Finally, to advance the science of health literacy further, instrument development should be considered. Specifically, the REALM-Teen and Spanish version of the STOFHLA would be more specific when studying an adolescent or Hispanic population. In addition, while effective in screening for limited health literacy, neither the REALM nor the STOFHLA fully capture the construct of health literacy. Therefore, new instruments are needed to facilitate future health literacy research in a variety of patient populations within both the active-duty military population as well as the civilian population.
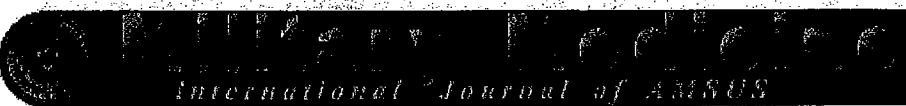
REFERENCES

1. HHS. *Healthy People 2010: Understanding and Improving Health: Office of Disease Prevention and Health Promotion.* Washington, DC; 2000.
2. Institute of Medicine, National Academies. *Health Literacy: A Prescription to End Confusion.* Washington, DC: The National Academies Press; 2004.
3. Kirsch IS, Jungeblut A, Jenkins L, Kolstad A. *Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey.* 3rd ed. Washington, DC: U.S. Department of Education, National Center for Education Statistics; 2002.
4. Guilford M, Morgan M. *Access to Health Care.* New York, NY: Routledge; 2003.
5. Jaarsma T, Dassen T. The relationship of nursing theory and research: the state of the art. *J Adv Nurs.* 1993;18(5):783-787.
6. Fawcett J. *The Relationship of Theory and Research.* 3rd ed. Philadelphia, PA: F.A. Davis; 1999.
7. LoBiondo-Wood G, Haber J. *Nursing Research: Methods and Critical Appraisal for Evidence-Based Practice.* 6th ed. St Louis, MO: Mosby; 2006.
8. Doak CC, Doak LG, Root JH. *Teaching Patients With Low Literacy Skills.* 2nd ed. Philadelphia, PA: J.B. Lippincott; 1996.
9. Rosenstock IM, Strecher VJ, MH MHB. Social learning theory and the Health Belief Model. *Health Educ Q.* 1988;15(2):175-183.
10. Glanz K, Rimer BK, Lewis FM. *Health Behavior and Health Education: Theory, Research and Practice.* 3rd ed. San Francisco, CA: Jossey-Bass; 2002.
11. Twente. Health Belief Model. http://www.tcw. utwente.nl/theorieenoverzicht/Theory%20clusters/ Health%20Communication/Health_Belief_Model.doc/. Accessed March 2008.
12. Carmona RH. Preventing obesity with education. *J Am Diet Assoc.* 2005;105(5/S9).
13. Davis TC, Williams MV, Marin E, Parker RM, Glass J. Health literacy and cancer communication. *CA Cancer J Clin.* 2002;52(3):134-149.
14. Janz NK, Champion VL, Strecher VJ. The Health Belief Model. In: Glanz K, Rimer BK, Lewis FM. *Health Behavior and Health Education: Theory, Research and Practice.* 3rd ed. San Francisco, CA: Jossey-Bass; 2002.
15. Rimer BK. Perspectives on intrapersonal theories of health behavior. In:Glanz K, Rimer BK, Lewis FM. *Health Behavior and Health Education: Theory, Research and Practice.* 3rd ed. San Francisco, CA: Jossey-Bass; 2002.
16. Kelli B. Health Belief Model. University of South Florida Community and Family Health. 1999. http://hsc.usf.edu/~kmbrown/Health_Belief_Model_ Overview.htm. Accessed April 2006.
17. Baranoski T, Perry CL, Parcel GS. How individuals, environments, and health behavior interact: Social cognitive theory. In: Glanz K, Rimer BK, Lewis FM. *Health Behavior and Health Education: Theory, Research and Practice.* 3rd ed. San Francisco, CA: Jossey-Bass; 2002.
18. Lewis FM. Perspectives on models of interpersonal health. In: Glanz K, Rimer BK, Lewis FM. *Health Behavior and Health Education: Theory, Research and Practice.* 3rd ed. San Francisco, CA. Jossey-Bass; 2002:214-245.
19. Bandura A. Social cognitive theory: an agentic perspective. *Annu Rev Psychol.* 2001;52:1-26.
20. Stone D. Social cognitive theory. http://hsc.usf. edu/~kmbrown/Social_Cognitive_Theory_Overview. htm. Accessed April 2006.
21. Bandura A. Health promotion by social cognitive means. *Health Educ Behav.* 2004;31(2):143-164.

22. Perry CL, Williams CL, Veblen-Mortenson S, et al. Project Northland: outcomes of a community-wide alcohol use prevention program during early adolescence. *Am J Public Health*. 1996;86(7):956-965.

23. Rogers LQ, Matevey C, Hopkins-Price P, Shah P, Dunnington G, Courneya KS. Exploring social cognitive theory constructs for promoting exercise among breast cancer patients. *Cancer Nurs*. 2004;27(6):462-473.

24. Choi J, Yu A, Bakken S. Tailored Web-based family educational materials in NICU. MEDINFO2004. http://cmbi.bjmu.edu.cn/news/report/2004/med info2004/pdffiles/papers/055_d040004367.pdf. Accessed March 2007.

25. Wolf MS, Davis TC, Osborn CY, Skripkauskas S, Bennett CL, Makoul G. Literacy, self-efficacy, and HIV medication adherence. *Patient Educ Couns*. 2007;65(2):253-260.

26. Sarkar U, Fisher L, Schillinger D. Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? *Diabetes Care*. 2006;29(4):823-829.

27. Zarcadoolas C, Pleasant AF, Greer DS. *Advancing Health Literacy: A Framework for Understanding and Action*. San Francisco, CA: Jossey-Bass; 2006.

28. Baker DW. The meaning and the measure of health literacy. *J Gen Intern Med*. 2006;21:878-883.

29. Paasche-Orlow MK, Wolf MS. The causal pathways linking health literacy to health outcomes. *Am J Health Behav*. 2007;31:S19-S26.

30. Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int*. 2000;15(3):259-267.

31. Manganello JA. Health literacy and adolescents: a framework and agenda for future research. *Health Educ Res*. 2008;23(5):840-847. Epub 2007 Nov 17.

32. Davis TC, Wolf MS, Arnold CL, et al. Development and validation of the rapid estimate of adolescent literacy in medicine (REALM-Teen): a tool to screen adolescents for below-grade reading in health care settings. *Pediatrics*. 2006;118(6):e1707-1714.

33. Dolan NC, Ferreira MR, Davis TC, et al. Colorectal cancer screening knowledge, attitudes, and beliefs among veterans: does literacy make a difference? *J Clin Oncol*. 2004;22(13):2617-2622.

34. Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Fam Med*. 1993;25(6):391-395.

35. DoDHealthAffairs. Office Web site of the Assistant Secretary for Defense (Health Affairs): Force Health Protection and Readiness; 2008. http://fhp.osd.mil/. Accessed March 2008.

36. Kutner M, Greenberg E, Jin Y, Paulsen C. *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. U.S. Department of Education. Washington, DC: National Center for Education Statistics; 2006.

37. Berkman ND, DeWalt DA, Pignone MP, et al. *Literacy and Health Outcomes*. Rockville, MD: Agency for Healthcare Research and Quality; 2004. Evidence Report/Technology Assessment no. 87.

38. Dewalt DA, Berkman ND, Sheridan S, Lohr KN, Pignone MP. Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med*. Dec 2004;19(12):1228-1239.

Chapter 7. Manuscript 4 – Data Analysis

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Health Literacy Rates in a Sample of

Active-Duty Military Personnel

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Abstract

The results reported in this paper are from a larger descriptive study examining the health

literacy rates in active-duty military personnel receiving health care within a culture of

universal access. The purpose of this paper is to describe the health literacy skills among

a sample of active-duty military personnel with comparison to the national population.

Data were collected using the shortened version of the Test of Functional Health Literacy

in Adults (S–TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM)

in a convenience sample of 155 active-duty subjects at a major military hospital from

January 2007 through May 2007. Results indicate that military personnel have adequate

health literacy skills although variations were noted based on health training and

race/ethnicity. While the S-TOFHLA was found to be a practical tool for assessing

health literacy in a high-tempo health care setting, additional reliability and validity

testing is needed.

Introduction

At least one-third of the United States population suffers from limited health literacy.[1,2] Limited health literacy prevents patients from effectively using their respective health system and has been linked to overweight/obesity, poorer health status, lower use of preventive services, and higher health care costs.[1,3] Higher rates of limited health literacy have also been found in individuals who are non-Caucasian, have lower education levels, and/or income, and who are males.[1,4,5] Results from the recent 2003 National Assessment of Adult Literacy (NAAL) indicate that on a 4-level scale ranging from below basic to proficient health literacy, only 25-million adults in the United States have proficient health literacy with the majority of the adults having intermediate health literacy. Moreover, 75-million adults had health literacy skills at the basic or below basic level.[4] When these adults encounter the health care system, they are likely to have difficulty with routine reading requirements, such as reading prescription bottles, food labels, appointment slips, self-care instructions, and health education brochures.[6]

The Institute of Medicine (IOM) has noted that active-duty military personnel, particularly new recruits, may be at risk for limited health literacy. The IOM has also recommended that the Department of Defense (DoD) develop programs to reduce the negative effects of limited health literacy such as producing health materials for use in the Military Health System (MHS) that are clear and written at an appropriate level.[1] However, while health literacy has been studied in the veteran population,[7] to date there are no published research studies focusing on health literacy rates and skills in the active-duty military population. To address this gap in research, a descriptive study at a major military medical center was conducted to examine the health literacy rates among a

sample of active-duty military receiving health care within a culture of universal access.

Universal access to health care is characterized as having both financial (health insurance

coverage) and structural access to care as well as lack of personal barriers to care such as

culture or sociological attitudes and perceptions. [8] Structural access to care exists when

an individual has a regular place of health care such as the MHS.[8,9] Although active-duty

military personnel have financial and structural access to care, there may be individual or

personal barriers to health care among service members. Thus, while active-duty military

personnel receive health care within a culture of universal access, there may only be

"near universal access" due to real or perceive personal barriers to receiving or obtaining

health care."[8]

The results reported in this article are from a larger study and address the first and

third specific aims. The purpose of the first aim was to identify and describe the literacy

skills and health literacy skills among a sample of active-duty military personnel using

the shortened version of the Test of Functional Health Literacy in Adults (S–TOFHLA)

and the Rapid Estimate of Adult Literacy in Medicine (REALM). The second aim of the

study was to explore relationships between socio-demographic characteristics and health

literacy skills. The third aim, considered a secondary aim, was to evaluate the reliability

and validity of the S-TOFHLA, and the practicality of using the S-TOFHLA at a high-

tempo military health care setting.

Background

Literacy is a complex construct, but is generally defined as the ability to read and

write or have knowledge of a particular subject or field.[10] First identified in 1974, health

literacy is also a complex construct which is commonly defined from a skills-based

perspective as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[11] This definition was developed for the National Library of Medicine (NLM)'seminal review on health literacy and was subsequently adopted by the IOM and Healthy People 2010.[12] The definition was also used to guide the research study conducted in this study. Achieving proficient health literacy is affected by individual ability, the suitability of the health information from a health perspective, and/or the socio-cultural environment of the individual. [1, 2, 12]

Although a new and emerging field of science, health literacy is now recognized as an important aspect of health promotion and disease prevention.[1, 12, 13] In the military, limited health literacy may be contributing to disparities in health care utilization and improved health status despite universal access to health care, services, and information through the MHS. Consider, that in the context of the culture of the MHS, gender, race, educational level, and income should not impact the availability of health services. The degree to which active duty military personnel are able to obtain health information and services needed to make appropriate health decisions, and improve health status is equal. All active-duty personnel have universal access to health care, and yet, according to the 2005 DoD Survey of Health Related Behaviors, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes.[14] For example, even with universal access to care, rates of overweight/obesity and hospitalization lag behind health improvement goals set in Healthy People 2010 (& 2000 for hospitalizations). Further, even within a culture that emphasizes health promotion and disease prevention, active-duty military personnel do

not currently meet health promotion objectives in such areas as blood pressure checks

(81.8% vs. 95%) and cholesterol checks (57.2 vs. 80% objective).[14]

Methods

Study Population

This descriptive study was conducted by collecting data from a convenience

sample of active-duty military personnel between January and May 2008 at a major

military medical center. Subjects, permanent staff, visitors, and patients, were recruited

using flyers posted in the waiting room of a family practice clinic.

Data Collection and Instrumentation

The study was approved by the Institutional Review Boards (IRB) as a minimum

risk human use protocol. Three data collection instruments were used: a socio-

demographic collection sheet, the S-TOFHLA, and the REALM. A total of 155 subjects

were enrolled and all subjects completed a written consent form and a Health Insurance

Portability and Accountability Act (HIPPA) form. The inclusion criteria were: being on

active-duty, a willingness to participate, and the ability to read and understand English

and answer a questionnaire. Exclusion criteria consisted of an uncorrected visual

impairment above 20/100, speech impairment, central nervous system disorders that

effect reading and speaking, and inability to give consent.

The socio-demographic data collection sheet was used to collect information

related to gender, age, pay grade or service rank, educational level, race/ethnicity, and

marital status. Subjects were also asked to report whether they had received health

professional training such as a combat medic and whether the subject was employed in a

health care role.

After completion of the socio-demographic collection sheet, subjects were then asked to complete the S-TOFHLA and the REALM. The S-TOFHLA is a the shortened version of the Test of Functional Health Literacy in Adults (TOFHLA) which measures functional health literacy skills or the ability to read and understand health-related materials. The S-TOFHLA consists of 4 numeracy items and 2 prose passages and is a time-limited survey that can be administered in approximately 12 minutes.[6]

The numeracy component of the S-TOFHLA assesses quantitative health literacy skills by testing the ability of subjects to read and understand numerical information in the form of prescription bottle labels, an appointment slip, and glucose score. The two prose passages test reading comprehension in a health care setting at the 4th grade level for passage A (x-ray preparation for gastrointestinal series) and 10th grade level for Medicaid rights and responsibilities. Reading comprehension is tested by having the subject circle the letter of the word (out of 4 words) the subject believes should go in the blank. This testing approach is known as the Cloze procedure.[6]

Construct validity for the TOFHLA and S-TOFHLA were established using actual hospital medical texts for both the reading comprehension and numeracy subtexts while concurrent validity has been shown by demonstrating statistical significant correlations between the REALM and the Wide Range Achievement Test-Revised (WRAT-R).[6] The REALM is a time-limited 66-item instrument that measures only the ability to read and correctly pronounce a list of words commonly seen in a medical setting.[15] The REALM was administered to subjects to assess the subject's estimated reading grade level and to facilitate the assessment of the S-TOFHLA's reliability in a military population.

Like the TOFHLA, the S-TOFHLA was developed and tested in an urban public hospital in Atlanta, Georgia. During the S-TOFHLA's developmental testing in 1977, the S-TOFHLA was shown to have good internal consistency as reflected by a Cronbach's alpha of .68 for the 4 numeracy items and .97 for the 36 Cloze items in the 2 prose passages comprising the reading comprehension section. Testing results also demonstrated a correlation between the numeracy score and the reading comprehension score was .60 . The correlation between the S-TOFHLA and the REALM was .80. Finally, during developmental testing of the S-TOFHLA, correlations for subscores of the numeracy and Cloze sections were .61 and .81 respectively with all correlations were significant at $p < .001$.[6]

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS). The criterion for statistical significance for all inferential statistical procedures was set at the p level of 0.05. Data were collected at the nominal, ordinal, and scale level and sample characteristics and study variables were summarized using descriptive statistics (mean, standard deviation (SD), frequency distributions) and percentages for categorical variables. Average scores across demographic subgroups were compared using a two group (independent) samples t-test and analysis of variance (ANOVA). Cronbach's alpha was used to assess the reliability (internal consistency) of the S-TOFHLA on the numeracy and Cloze items and a correlation between the two sections performed using Pearson's product moment correlation. Pearson's product moment correlation was also used to compare the S-TOFHLA with the REALM.

Results

Sample Characteristics

A summary of demographic characteristics is contained in Table II. The mean

age for the subjects was 29.3 (SD = 8.08) with 55 subjects (35.9%) under the age of 24

years and 74 subjects (48.4%) between the ages of 24 years and 39 years. Fifty-three

percent of subjects were females. Overall, subjects self-identified themselves as

White/non-Hispanic (50.3%) and African-American/non-Hispanic (28.4). Eighty-two

percent (81.6%) of the subjects were enlisted with 69 subjects (46.9%) at the E1-E4

grades and 52 subjects (35.4%) at the E5-E9 grades. Ninety-four percent of subjects had

an educational level at the high school equivalent (GED) or higher and forty-nine percent

were married. Ninety-nine percent of the subjects were found to have adequate health

literacy skills as measured by the S-TOFHLA. Out of 152 subjects, one hundred forty-

four had estimated reading grade levels at the 9th grade level or higher as measured on the

REALM. See Tables I, II, and III.

Data Analysis – Socio-Demographic Subgroup Comparisons

Independent-samples t-tests were conducted to compare S-TOFHLA scores by

gender and health training (yes or no) after testing underlying assumptions. The

Kolmogorov-Smirnov test was used to validate the assumption of normality.[16] Although

the Kolmogorov-Smirnov tests were significant for both gender and health training

(p=.000), visual inspection of the distribution and the Normal and Detrended Normal Q-

Q Plots indicated distribution of scores were reasonably normal for conducting the tests.[17]

The homogeneity of variance test for training was also significant at $F_{(60.95)} = 6.076$;

p = .015. Test results were significantly different for subjects with health professional training (M = 94.47, SD = 5.02) than those without training (M = 89.41; SD = 7.75) at t(153) = 4.49; p = .000. According to the table set forth in Huck (2005), the magnitude of the differences in the means was moderate (eta squared = .12).

One-way between groups ANOVA were also conducted to evaluate the impact of marital status, age, pay grade/rank, race/ethnicity, and highest education level on S-TOFHLA scores. After considering the sample size(s), categorical sizes, the Levene's test, and visual inspection of the distributions and plots, Q-Q plots, the distribution of scores appeared reasonably normal for purposes of conducting the ANOVA, particularly since violations of normality assumption usually do not reduce the validity of results.[17-19] Testing indicated that there were no significant differences based on marital status, age (recoded into 4 groups), pay grade/rank (recoded into enlisted, non-commissioned officers, and officer), and education level. There was a statistically significant difference in racial groups (recoded to 4 groups by combining Asian and other) at the p <.05 level in S-TOFHLA scores [F(3, 43) = 5.7, p = .002]. See Table IV. The effect size, calculated using eta squared was .13 for a moderate to large effect.[16-18, 20] Post-hoc comparisons using Tukey HSD test indicated that the mean score for Whites/non-Hispanics (M = 93.41, SD = 5.14) was significantly different from African-Americans/non-Hispanic (M = 87.77, SD = 9.06) (p = .000). No other significant differences between race/ethnicity groups were found. See Table IV.

Based on the study's findings, a two-way between groups ANOVA was conducted to further explore the impact of training and race/ethnicity on S-TOFHLA scores. The Levene test was not met so a more stringent significant value of p = .01 was

used to evaluate the results.[16] There were statistically significant main effects for both race/ethnicity [$F_{(3,139)} = 4.61$, $p = .004$] and training [$F_{(3, 139)} = 13.8$, $p = .000$] and both had a medium effect size (partial eta square = .09). Post-hoc comparisons using Tukey HSD test indicated a significant difference between White\non-Hispanics and African-Americans at $p = .000$. The interaction effect did not reach statistical significance.

Data Analysis – Reliability and Correlation of S-TOFHLA to REALM

Cronbach's alpha for the study's 4 numeracy S-TOFHLA items was low at .38, but moderately reliable at .70 for the 36 Cloze items. As measured by the Pearson product-moment correlation coefficient, the association between the numeracy score and the reading comprehension score was low at $r = .20$ with a statistical significance of $p = .013$. The correlation coefficient (r squared) was also low at .04 of variance. The association between the S-TOFHLA and the REALM was low at $r=.10$ ($N = 155$, $p < .05$) with a correlation coefficient of only .01 of variance.

Discussion

Statistical comparisons between the NAAL 2003 and the results of this study cannot be made since different measurement instruments and operational definitions were utilized.[4] However, general comparisons between the results of this study and NAAL 2003 results suggest that the sample of active-duty military personnel have higher levels of literacy (estimated reading grade level) and health literacy skills than the national population. Using the REALM,[15] 94.6% of active-duty personnel had an estimated reading level at the 9th grade level or above and a literacy skill level that suggests that the service member could read most patient education materials. In contrast, the NAAL

2003 results showed that only 13% of national population had proficient level of prose, document, or quantitative (numeracy) literacy with proficient being defined as the ability to perform complex and challenging literacy activities. Moreover, the NAAL 2003 results showed there were fewer adults with proficient prose and document literacy than in 1992 during the National Adult Literacy Survey.[21] While not discounting the IOM's concerns over military recruits, the findings from this study on literacy suggest that military personnel are educated and able to perform challenging literacy activities.

As with literacy, S-TOFHLA scores for the sample of active-duty military personnel indicate a higher overall level of health literacy skills than exists in the national population. Results from the study showed that 99.4% of military subjects had adequate health literacy skills whereas only 12% of the national population has proficient health literacy with 53% and 24% at the intermediate and basic/below basic level, respectively. Moreover, general comparisons across socio-demographic subgroups such as age, race/ethnicity, and gender also indicate that the military personnel have overall higher levels of health literacy for all sub-groups with African-Americans continuing to demonstrate lower health literacy levels than other race/ethnicities. See Table V.

Within the sample of active-duty military personnel, significant differences were found between personnel with and without health professional training and based on race/ethnicity. The significant difference based on health training was not unexpected. However, further analysis also revealed that within the subgroup of race/ethnicity, the only significant difference was between White/non-Hispanics and African-Americans who also had the lowest mean S-TOFHLA score of any subgroup when 4 subgroup classifications were considered (White/non-Hispanic, African-Americans, Hispanics, and

other). See Table II. This finding is consistent with both the 1992 National Adult

Literacy Survey and NAAL 2003 and the position of the U.S. Surgeon General on health

disparities.[22, 23] In addition, several studies have also reported an association between

limited health literacy and race/ethnicity [1, 24-29] including one that specifically noted that

African-Americans had significantly lower health literacy than Whites.[30] Thus, estimates

of mean health literacy adjusted for training suggests that the fact that African-Americans

had lower health literacy skills than other race/ethnic groups in this study was not merely

because of differences in training. Clearly, the existence of such a significant difference

in a culture of universal access suggests that other noneconomic determinant(s) may

account for this disparity and supports the need for additional health literacy research

with a health disparity focus.

Instrumentation and Study Limitations

Reliable instruments enhance the power of a study to detect significant

differences or relationships occurring in a study sample. Although the S-TOFHLA and

REALM have been found reliable,[6] high reported reliability values do not guarantee that

the instruments will be valid in another sample or different population.[31] The results of

this study raise concerns in the population over the reliability of the S-TOFHLA's

numeracy section and the instrument's validity based on the S-TOFHLA's correlation

with the REALM.[31] These concerns over reliability and validity may be due to a lack of

variability because so many scores clustered at the high end of the S-TOFHLA scale.

Further instrumentation testing is clearly needed in the active-duty military population

and the findings from this study should be considered in light of these concerns over

reliability and validity. Nevertheless, until such time as additional tools are developed,

the S-TOFHLA and REALM are the two primary instruments available for assessing health literacy skills and both of these instruments were found to be easy administer and score in a high-tempo clinic.

In addition to instrumentation, there were two other limitations. First, subjects were drawn from a convenience sample of volunteers therefore individuals with actual or perceived lower literacy/health literacy skills may have opted not to participate. Second, the sample was drawn from a health care environment where individuals either had health training or may have developed higher health literacy due to working in a health care environment. Thus, further research in a non-health care military environment is warranted.

Conclusion

The results of this study demonstrate a favorable health literacy rate in military personnel as compared to the health literacy levels for the national population. However, the existence of a significant difference in health literacy skills between White/non-Hispanic and African-Americans within a culture of universal access to care suggests that other noneconomic determinant(s) may account for this disparity and supports the need for further health literacy research.

References

1. IOM. *Health Literacy: A Prescription to End Confusion (Bohlman, L.N., Panzer, A.M., Kind, D.A., eds)*. Institute of Medicine of the National Academies:Washington, D.C.: The National Academies Press; 2004.

2. Kirsch IS, Jungeblut A, Jenkins L, Kolstad A. *Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey (3rd ed)*. Washington, D.C.: U.S. Department of Education: National Center for Education Statistics; 2002

3. Carmona RH. Preventing obesity with education. *J Am Diet Assoc.* 2005;105(5/S9).

4. Kutner M, Greenberg E, Jin Y, Paulsen C. *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006-483)*. U.S. Department of Education. Washington, DC: National Center for Education Statistics 2006.

5. Carmona RH. Keynote Speech for National Managed Health Care Congress Summit: Reducing Racial and Cultural Disparities in Health Care: What Actions Now? April 27, 2004; http://www.surgeongeneral.gov/news/speeches/managedcare031103.htm.

6. Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss JR. Development of a brief test to measure functional health literacy. *Patient Educ Couns.* Sep 1999;38(1):33-42.

7.   Dolan NC, Ferreira MR, Davis TC, et al. Colorectal Cancer Screening

        Knowledge, Attitudes, and Beliefs Among Veterans: Does Literacy Make a

        Difference? *Journal of Clinical Oncology.* 2004; 22(13):2617-2622.

8.   Guilford M, Morgan M. *Access to health care.* New York, NY: Routledge; 2003.

9.   Hymann JJ, Reid BC, Mongeau SW, York AK. The military oral health care

        system as a model for elimination disparities in oral health. *Journal of American*

        Dental Association. 2006;137:372-378.

10.   Dictionary.Com. Literacy. http://dictionary.reference.com/search?q=literacy.

11.   Selden CR, Zorn M, Ratzan S, Parker RM. *National Library of Medicine Current*

        Bibliographies in Medicine: Health Literacy (NLM Pub. No. CBM 2000-1).

        Bethesda, MD: U.S. Department of Health and Human Services/National

        Institutes of Health; 2000.

12.   HHS. Healthy People 2010: Objectives for improving health (Part A: focus areas

        1-14) In: U.S. Department of Health and Human Services. Washington DC, ed.

        Vol Volume 1 (2nd ed.); 2000.

13.   Carmona RH. Speech on September 19, 2003 to Pfizer Sixth National Health

        Literacy Conference: Health Literacy: Key to improving America's Health.

        http://www.surgeongeneral.gov/news/speeches/healthlit09192003.htm.

14.   Bray RM, Hourani LL, Olmsted KLR, et al. DoDHA (2006). Department of

        Defense 2005 Survey of Health Related Behaviors Among Active Duty Miltiary

        Personel. Prepared by RTI International, December 2006. 2006.

15.   Davis TC, Long SW, Jackson RH, et al. Rapid estimate of adult literacy in

        medicine: a shortened screening instrument. *Fam Med.* Jun 1993;25(6):391-395.

16. Huck SW. *Reading statistics and research.* Boston, MA: Pearson Education Inc.; 2008.

17. Munro BH. *Statistical Methods for Health Care Research, 4th ed.*: Lippincott Williams & Wilkins: Philadelphia, PA.; 2005.

18. Tabachnick BG, Fidell LS. *Computer Assisted Research Design and Analysis.* Needham Heights, MA:: Allyn and Bacon; 2001.

19. Tabachnick BG, Fidell LS. *Using multivariate statistics.* 4th ed. New York: NY: HarpersCollins; 2001.

20. Cohen J. *Statistical power analysis for the behavioral sciences* 2nd ed. Hillsdale, NJ: Lawrence Erlbuam Associates; 1988.

21. Kutner M, Greenberg E, Jin Y, Boyle B, Hsu Y-c, Dunleavy E. *Literacy in everyday life: Results from the 2003 National Assessment of Adult Literacy* 2007.

22. Carmona RH. Speech on November 8, 2004. Press conference to launch "U.S. Surgeon General's Family History Initiative" at the National Press Club November 16, 2004.

23. Carmona RH. Speech on July 9, 2004 to Academy of General Dentistry 2004 Annual Meeting: Dentists' Many Roles in Prevention, Public Health Preparedness, Eliminating Health Disparities, and Improving Health Literacy. October 18, 2004; http://www.hhs.gov/surgeongeneral/news/speeches/07092004.htm.

24. Arnold CL, Davis TC, Berkel HJ, Jackson RH, Nandy I, London S. Smoking status, reading level, and knowledge of tobacco effects among low-income pregnant women. *Prev Med.* Apr 2001;32(4):313-320.

25. Beers BB, McDonald VJ, Quistberg DA, Ravenell KL, Asch DA, Shea JA. Disparities in Health literacy between African American and non-African American Primary Care Patients. *Abstract. Journal of General Internal Medicine.* 2003;18 (Supplement 1):169.

26. Bennett CL, Ferreira MR, Davis TC, et al. Relation between literacy, race, and stage of presentation among low-income patients with prostate cancer. *J Clin Oncol.* Sep 1998;16(9):3101-3104.

27. Gazmararian JA, Baker DW, Williams MV, et al. Health literacy among Medicare enrollees in a managed care organization. *Jama.* Feb 10 1999;281(6):545-551.

28. Schillinger D, Grumbach K, Piette J, et al. Association of Health Literacy with Diabetes Outcome. *Jama.* 2002;288(4):475-482.

29. Berkman ND, DeWalt DA, Pignone MP, et al. *LIteracy and health outcomes. Agency for Healthcare Research and Quality. Evidence Report/Technology Assessment No. 87, (Prepared by RTI International-University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016). AHRQ Publication No. 04-E007-2. Rockville, MD: January 2004.* . 2004.

30. Shea JA, Beers BB, McDonald vJ, Quistberg DA, Ravenell KL, Asch DA. *Family Medicine.* 2004;36(8):575-581.

31. Burns N, Grove SK. *The practice of nursing research: Conduct, critique, and utilization* 5th ed. St. Louis, MO: Elsevier; 2005.

Table I.
Variables, Definitions, and Applicable Measures

Variable Name	Conceptual Definition	Operational Definition	Measure
Literacy	Constellation of skills including reading, writing, basic , numeracy, & speech/speech comprehension in specific contexts [prose, document and quantitative] (Kirsch, 2001)	The grade reading level (or reading difficulty level)(literacy skills) - in the health context, the ability to read at the 10th grade level or above.	- REALM – Estimated Reading Grade Level
Health Literacy	Degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions	Subjects ability to read and unders the things they commonly encounter in the health care setting	- S-TOFHLA - overall assessment of health literacy - REALM – decoding measurement of adult literacy in medicine for adults
HC/IP – Culture & Society	Shared ideas, meanings, and values acquired by individuals as members of society. Includes social determinants of health such as native language, SDCs, along with influences of mass media and the plethora of health information sources available through electronic sources	*SDCs - Gender, Marital Status, Race/Ethnicity, and Pay grade/ Rank plus health professional status	-Gender -Age -Rank/Pay grade -Race/Ethnicity -Marital Status -Education level -health professional train status (RN, medic, etc.) -health care position -Financial and structural access to care (MHS)

* A socio-demographic (SDC) collection sheet was used to collect self-reported data on gender, marital status, race/ethnicity, pay grade/rank, and whether the service member had health professional training, e.g., R.N., M.D., combat medic, or worked in a health care position.

Table II
Summary of Demographic Characteristics

Characteristics	No. of Cases	Percent of Total
Age, mean years (SD) *	153	29.3 (8.08)
Less than 24 years	55	35.9
25-39 years	74	48.4
40-49 years	24	15.7
Gender		
Male	73	47.1
Female	82	52.9
Marital Status		
Single, never married	59	38.3
Married	76	49.4
Separated/Divorced	19	12.3
Widowed	0	0
Current pay grade (E1-O10)		
E1	2	1.4
E2	7	4.8
E3	27	18.4
E4	33	22.4
E5	30	20.4
E6	12	8.2
E7	7	4.8
E8	2	1.4
O1	8	5.4
O2	2	1.4
O3	12	8.2
O4	2	1.4
O5	2	1.4
O6	1	.7
Highest level of education		
Did not graduate from high school	1	.6
GED certificate	4	2.6
High School Diploma	28	18.1
Some College, but not 4-year college degree	77	49.7
4-year college degree or higher	45	29.0
Race/Ethnicity		
White/Non-Hispanic	78	50.3
African American/Non-Hispanic	44	28.4
Hispanic	17	11.0
American Indian/Alaskan Native	2	1.3
Asian	6	3.9
Other	8	5.2
Has received health professional training		
Yes	60	38.7
No	95	61.3
Work at military hospital in health care position		
Yes	89	57.4
No	66	42.6

*Not all respondents answer all questions on the SCD survey, so the "n" varies between questions

Table III
Summary of Study Variables

Study Variable	No. of Cases	Percent of Total
S-TOFHLA-numeracy (1-100 total score),		
Mean score (SD) 91.4-7.4	155	
Median 93.0		99.4
Adequate health literacy (Score of 67-100)	154	
REALM, (1-66 total score)		
Mean score (SD) 64.5-2.8	152	
Median 65.0		
9th grade reading level or above	144	94.6
7th – 8th grade reading level or above	7	4.7
4th -6th grade reading level or above	1	.7

*Not all respondents answered all questions on the socio-demographic survey, so the "n" varies between questions

Table IV
One-Way ANOVA for S-TOFHLA based on Race/Ethnicity

Category	Sample Size	M	SD
White/non-Hispanic	78	93.4103	5.14071
African American	44	87.7727	9.06787
Hispanic	17	91.5294	6.92024
Other	8	88.1250	7.84561

Source	Sum of squares	df	MS	F	P
Between Groups	975.325	3	325.108	6.689	.000
Within Groups	6767.709	143	47.327		

* Levene Statistic = 6.985, p = .000
* Brown-Forsythe: $F(3,43) = 5.718$, p = .002

Table V
General Comparison to National Population

Military Personnel	Military Study Results	NAAL 2003 Results [4, 21]
Literacy	94.6% with 9th grade reading level or above	- 13% of national population with proficient* prose,** document,*** and quantitative literacy****
Health Literacy		
Overall Health Literacy	99.4% with adequate health literacy skills	- 12% with proficient level of health literacy - 53% intermediate level of health literacy - 24% with basic or below basic level of health literacy
Gender	No statistical difference between males and females	- 11% of men and 12% women had proficient health literacy
Age - Up to 24 years - 24-39 years - 40-49 years	No statistical difference between age groups and majority had adequate health literacy skills	- 19% had proficient health literacy (16-24 years) - 16% had proficient health literacy (24-39 years) - 12% had proficient health literacy (40-49 years)
Race/Ethnicity -White/non-Hispanic - African American - Hispanic - Other	- All groups with adequate health literacy. - Whites/non-Hispanics (M=93.41, SD=5.14) was significantly different from African- Americans/non-Hispanic (M=87.77, SD=9.06).	- White/non-Hispanic had 14% proficient health literacy - African American had 2% proficient health literacy - Hispanic had 4% proficient health literacy - Other had 28% proficient health literacy (18% Asian; 7% American Indian/Alaskan Native; 3% multi-racial)
Education - Less than high school - High school/GED - Some college - 4-year college/higher	No statistical differences between groups	- 8% had proficient health literacy (less than high school) - 7% had proficient health literacy (high school/GED) - 30% had proficient health literacy (Some college) -60% had proficient health literacy (4-year college/higher)

*Proficient means individual can perform complex and challenging literacy activities.

**Prose literacy means the knowledge and skills needed to search, comprehend, and use information from continuous texts, e.g., news, brochures, and instructional materials.

***Document literacy means the knowledge and skills needed to search, comprehend, and use information from non-continuous texts in various formats, e.g., job applications, maps; and food labels.

****Quantitative literacy means the knowledge and skills required to identify and perform computations, either alone or sequentially, using numbers embedded in printed materials, e.g., balancing a checkbook.

Chapter 8. Manuscript 5 – Data Analysis

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Date: Thursday - July 17, 2008 12:37 PM
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Running Head: PREDICTORS OF HEALTH LITERACY

Sociodemographic Characteristics as Predictors of Health Literacy

Within a Culture of Universal Access to Care

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Military Disclosure

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Abstract

Purpose: To describe the relationships between health literacy and sociodemographic

characteristics (SDCs) in a sample of adults with universal access to care.

Methods: In this descriptive study, the shortened Test of Functional Health Literacy (S-

TOFHLA) was used to explore relationships between SDCs (e.g., gender, age, race/ethnicity,

income, health training) and health literacy. Analyses were conducted using linear regression.

Results/Implications: Health training and being African American were the only significant SDC

predictors of health literacy skill level (p $\leq$ .001). Closing the gap in health literacy among

racial/ethnic groups is essential to reducing health disparities occurring at varying levels of

access.

Sociodemographic Characteristics as Predictors of Health Literacy

Within a Culture of Universal Access to Care

The report *Healthy People 2010* has two main goals: to help individuals of all ages increase life expectancy and improve their quality of life; and to eliminate gender, education, income, and race/ethnicity based health disparities among segments of the United States (U.S.) population (Department of Health and Human Services [HHS], 2000a). These goals are both interrelated and critical to improving the Nation's health. Improving health literacy skills among various populations will not only further the goal of eliminating health disparities (HHS, 2000b), but will also lead to improved quality of life and life expectancy (Institute of Medicine [IOM], 2004). Thus, relationships between health literacy and sociodemographic characteristics (SDCs) should be explored in a variety of populations and settings as a means of furthering the goals of *Healthy People 2010*, particularly the elimination of health disparities.

The purpose of this paper is to describe the results of a study conducted to explore relationships between SDCs (gender, age, education level, race/ethnicity, marital status, pay grade/rank, and health training) and health literacy in a sample of adults receiving health care within a culture of universal access. An individual has universal access when financial access (e.g., health insurance coverage) and structural access (a regular place to receive care) are present, and there are no known real or perceived barriers to care such as cultural or educational barriers (Guilford & Morgan, 2003; Hymann, Reid, Mongeau, & York, 2006). For example, although active-duty military personnel have financial and structural access to care through the military health system (MHS), limited heath literacy (educational barrier) may prevent individual service members from fully utilizing available preventive health services which exist within the MHS. Therefore, while active-duty military personnel receive health care within a culture of

universal access, there may only be "near universal access" at the individual service member

level due to personal barriers to receiving or obtaining health care (Guilford & Morgan, 2003).

Background

Literacy is the foundational construct of health literacy and is defined as the ability to

read and write, or have knowledge of a particular subject or field. Health literacy is generally

defined from a skills-based perspective as "the degree to which individuals have the capacity to

obtain, process, and understand basic health information and services needed to make

appropriate health decisions" (IOM, 2004). This definition has been used by the IOM in its

report on health literacy and *Healthy People 2010,* as well as in numerous research studies

including the one described in this article. Adequate health literacy depends upon a number of

factors such as individual ability, the suitability of the health information, and/or the socio-

cultural environment of the individual (IOM, 2004).

There are a number of benefits to achieving adequate health literacy such as the reduction

of health disparities (HHS, 2000b). Currently, at least one-third of the U.S. population suffers

from limited health literacy which is associated with poorer health status, lower use of preventive

services, and higher health care costs (IOM, 2004; Kirsch, Jungeblut, Jenkins, & Kolstad, 2002).

In addition, studies have also reported an association between limited health literacy and

race/ethnicity, lower education level, and a lack of access to health insurance (Kutner,

Greenberg, Jin, & Paulsen, 2006).

Notwithstanding the link between limited health literacy and health disparities or

sociodemographic status, there has been little health literacy research in populations with

universal or "near" universal access to health care (Dolan et al., 2004; Kutner et al., 2006). For

example, there are no published reports involving health literacy research in the active-duty

military population even though there are at least 1.3 million active-duty military members using

the MHS (Department of Defense [DoD], 2008; DoD Appropriations Bill, 2007). This lack of

research within a culture of universal access to health care is significant because the IOM has

noted in its report on health literacy that despite such access, populations such as active-duty

military personnel may be at risk for limited health literacy (IOM, 2004). Moreover, according

to *Healthy People 2010,* even with access to information and health care services, health

disparities may still exist in a culture of universal access as a result of limited health literacy

(HHS, 2000a; IOM, 2004).

To address the lack of research in adults within a culture of universal access, a descriptive

study was conducted at a major military medical center to examine the health literacy rates

among a sample of active-duty military personnel. The results reported in this article are from

the larger descriptive study and pertain to exploring the relationships between SDCs and health

literacy skills.

Theoretical Framework

The theoretical framework used to guide the descriptive study was the Health Literacy

Framework (HLF) as adapted for individuals with universal access to health care (IOM, 2004).

As indicated earlier, an individual has universal access to health care when the individual has

both financial and structural access to health care are present, without real or perceived barriers

impeding access to care (Guilford & Morgan, 2003). The HLF was chosen based on the

framework's simplicity, primary focus on health literacy skills, and the framework's adaptability

to research in populations such as active-duty military personnel.

The concepts of literacy and health literacy are interrelated and form the foundation of the HLF. Proficient literacy skills are necessary for an individual to have adequate health literacy skills. The two primary influences of overall health literacy skills are the individual and the health-related environments and situations in which an individual interacts. These environments and situations are represented by the term "health context" which consists of the following three sectors: culture and society, education system, and health outcomes and costs (IOM, 2004). Consistent with this study's purpose of examining health literacy rates and exploring relationships of health literacy to SDCs, the only sector of the HLF focused on was culture and society (IOM, 2004). In the military context, culture and society refer to both the values and ideas acquired prior to enlistment or commissioning, and those values and ideas acquired as part of the socialization and continued orientation into the military's culture.

Methods

General Approach and Sample

Between January and May 2008, a descriptive study was conducted at a major military medical center. Data were collected from a convenience sample consisting of 155 active-duty military personnel who were permanent staff, patients, or visitors at the medical center. Participants were recruited using flyers posted in the waiting room of a family practice clinic. The study was approved by two Institutional Review Boards as a minimum risk human use protocol. Prior to participation, all participants completed a written consent form and a Health Insurance Portability and Accountability Act (HIPPA) form.

Data Collection

Data were collected using three instruments: a sociodemographic collection sheet, the shortened Test of Functional Health Literacy (S-TOFHLA) and the Rapid Estimate of Adult

Literacy in Medicine (REALM). The inclusion criteria consisted of being an active-duty service member, a willingness to participate in the study, the ability to read and understand English, and the ability to answer a questionnaire. Participants were excluded from the study based on blindness, uncorrected visual impairment above 20/100, speech impairment, or if the participant suffered from a Central Nervous System disorder that negatively impacted the participant's ability to read, speak, or provide written consent.

Measurement Tools

A sociodemographic collection sheet was used to collect information on gender, age, education level, race/ethnicity, marital status, and health professional training. Participants were then asked to complete the S-TOFHLA and the REALM (see Table 1). The S-TOFHLA measures functional health literacy skills or the ability to read and understand health-related materials and consists of 4 numeracy items and 2 prose passages. The numeracy or quantitative health literacy items are used to test the ability of participants to read and understand numerical information in forms commonly seen in a medical environment (e.g., prescription bottle labels, an appointment slip). The two prose passages test reading comprehension in a health care setting at the fourth grade level for the first passage (x-ray preparation for gastrointestinal series) and at the tenth grade level for second passage (Medicaid rights and responsibilities). To complete the prose passages, participants were asked to circle the letter of the word (out of 4 words) the participant believes should go in the blank, which is known as the Cloze procedure (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). The S-TOFHLA can be administered in approximately 8-12 minutes (Baker et al., 1999).

Construct validity for the S-TOFHLA was established using actual hospital medical texts for both the reading comprehension and numeracy items. Concurrent validity for the S-

TOFHLA has been shown by demonstrating statistically significant correlations between the S-TOFHLA and the REALM (Baker et al., 1999). The REALM is a 66-item instrument that measures the ability to read and correctly pronounce a list of common medical terms (Davis et al., 1993). The REALM takes approximately 2-3 minutes to complete and was used to estimate the reading grade level in the study population.

The S-TOFHLA was developed in 1997 using an adult population from an urban public hospital in a large metropolitan area. During development, good internal consistency was established by a Cronbach's alpha of .68 for the 4 numeracy items and .97 for the 36 Cloze items in the reading comprehension section. Also, development testing demonstrated a correlation between the numeracy and the reading comprehension scores of .60. The correlation between the S-TOFHLA and the REALM was .80. Correlations for sub-scores of the numeracy and Cloze sections were .61 and .81, respectively. All correlations during the development of the S-TOFHLA were significant at $p < .001$ (Baker et al., 1999).

Statistical Plan

The Statistical Package for the Social Sciences (SPSS) was used for statistical analyses, including descriptive statistics (mean, standard deviation [SD], frequency distributions) and percentages for categorical variables. Average scores across demographic subgroups were also compared using an independent samples t-test, analysis of variance (ANOVA), and two-way between groups ANOVA. Standard (exploratory) multiple regression analysis was used to examine SDCs as predictors of health literacy skills in an adult sample consisting of active-duty military personnel. Statistical significance for all inferential statistics was set at the p-level of 0.05.

Results

Sample Characteristics

A summary of demographic characteristics is contained in Table 2. Fifty-three percent of participants were females. The mean age of the participants was 29.3 (SD = 8.08) with 55 participants (35.9%) under the age of 24 years and 74 participants (48.4%) between the ages of 24 years and 39 years. One-hundred twenty participants (81.6%) were enlisted personnel or noncommissioned officers while 27 participants (18.4%) were commissioned officers. Forty-four participants (28.4%) self-identified themselves as African Americans and 111 participants (71.6%) self-identified themselves as a member of a racial/ethnic group other than African American. Of these latter participants, 78 participants (50.3%) self-identified themselves as White/Hispanics, 17 participants (11.0%) as Hispanic, and 16 participants (10.4%) as American Indian/Alaskan Native, Asian or "other." Ninety-nine percent of the participants were found to have adequate health literacy skills as measured by the S-TOFHLA. Out of 155 participants, 144 participants had estimated reading grade levels at the ninth grade level or higher as measured by the REALM (see Tables 2 and 3).

Data Analysis - Group Comparisons

After considering the sample size(s), categorical sizes, the Levene's test, and visual inspection of the distributions and plots, Q-Q plots, the distribution of scores appeared normal for purposes of conducting independent samples t-tests and one-way between groups ANOVAs. Results of the independent samples t-tests showed that participants who had health professional training had significantly higher S-TOFHLA scores (M = 94.47, SD = 5.02) than those participants without training (M = 89.41; SD = 7.75), t(153) = 4.49; p ≤ .001. The magnitude of

the differences in the means was moderate according to the table set forth in Huck (2008) (eta squared = .12). Results from one-way ANOVA testing showed there were no significant differences based on marital status, age (recoded into 4 groups), pay grade/rank (recoded into enlisted personnel, noncommissioned officers, and officer), and education level. However, a statistically significant difference was found based on race/ethnicity in S-TOFHLA scores, F(3, 43) = 5.7, p = .002, (eta squared = .13). To ensure ample group size for ANOVA testing of race/ethnicity, the race/ethnicity variable was recoded into 4 subgroups of White/non-Hispanics, African Americans, Hispanics, and "other" by combining the subgroups of American Indian/Alaskan Native, Asian and "other." Results from the Tukey's honestly significant difference (HSD) test showed that the mean score for Whites/non-Hispanics (M = 93.41, SD = 5.14) was significantly higher as compared to African Americans (M = 87.77, SD = 9.06), p ≤ .001. There were no other significant differences based on race/ethnicity.

To further explore the impact of training and race/ethnicity on S-TOFHLA scores, a two-way between groups ANOVA was also conducted. Since the Levene's test was not met, a p value of 0.01 was set. The test revealed statistically significant main effects for race/ethnicity, F(3,139) = 4.61, p = .004, and training, F(3, 139) = 13.8, p ≤ .001, with both variables having a medium effect size (partial eta square = .09). The Tukey HSD test showed a significant difference between White/non-Hispanics and African Americans at p ≤ .001. The interaction effect did not reach statistical significance.

Regression Analysis

Since there are no published health literacy research studies on the active-duty military population, standard (exploratory) regression analysis was used to determine whether the study's

SDCs are effective predictors of health literacy as measured by the S-TOFHLA. After dummy coding categorical variables to fit the model, initial testing revealed that the assumptions of multicollinearity including tolerance statistics, normality, linearity, and homoscedasticity were met. Results showed the multiple R (.470) between the predictor SDCs and the S-TOFHLA was statistically significant, $F(7, 137) = 5.556$, $p \leq .001$. Twenty-two percent of the variance in S-TOFLA scores was explained by the model. When considered separately, two SDCs were found to be significant predictors of health literacy skill level: training with "no training" as the reference category ($\beta = .328$, $p \leq .001$), and race/ethnicity with African American as the reference category ($\beta = .285$, $p \leq .001$). African American was chosen as the reference category based on the results of the one-way and two-way ANOVAs and previous studies indicating that African Americans had lower health literacy when compared to other racial/ethnic groups (Kutner et al., 2006). The choice of African American as the reference category was also made to ensure that the subgroup sizes were adequate and the sample size requirement was met (Tabachnick & Fidell, 2001) (see Table 4).

Reliability and Correlation of Instruments

The Cronbach's alpha for the study's 4 numeracy S-TOFHLA items was low at .38, but moderately reliable at .70 for the 36 Cloze items. The Pearson product-moment correlation coefficient for the association between the numeracy score and the reading comprehension score was low at $r = .20$ with a statistical significance of $p = .013$. The correlation coefficient (r squared) was also low at .04 of variance. The S-TOFHLA and the REALM had a low association at $r = .10$ ($N = 155$, $p < .05$) with a correlation coefficient of only .01 of variance.

Discussion

Using the REALM, 144 participants had an estimated reading level at the 9th grade level or above. This suggests that the majority of participants could read most patient education material. This finding is encouraging when comparing the results of this study to the U.S. population as reflected in the 2003 National Assessment of Adult Literacy (NAAL). In the 2003 NAAL, only 13% of the population demonstrated a proficient level of prose, document or quantitative (numeracy literacy) with proficiency being defined as the ability to perform complex and challenging literacy activities (Kutner et al., 2006). Likewise, compared to the 2003 NAAL, participants in the study also had higher overall levels of health literacy. While only 12% of the U.S. population demonstrated proficient health literacy, 99% of participants had adequate health literacy skills as measured by the S-TOFHLA (Kutner et al., 2006). As with literacy, these findings are encouraging and suggest that the participants receiving care within a culture of universal access are educated and able to perform challenging health literacy tasks.

However, significant differences were noted on race/ethnicity and between participants with and without health professional training. The latter finding on health professional training was not an unexpected finding. Conversely, the finding that African Americans in an active-duty military population with universal access to health care had lower health literacy skills than participants from other racial/ethnic groups was unanticipated. All participants in this study receive health care within a culture of universal access where the degree to which participants are able to obtain health information and services needed to make appropriate health decisions, and improve health status is equal. Nevertheless, even when estimates of mean health literacy were adjusted for differences in health training background, for unexplained reasons African

Americans still had lower health literacy skills than other racial/ethnic groups (see two-way ANOVA results, above).

To better understand the impact of race/ethnicity on health literacy, a standard (exploratory) regression model was used to ascertain the predictive behavior of the 7 SDCs on health literacy. Results from the model indicated that of the 22% of the variance in S-TOFHLA scores, only health training and race/ethnicity were significantly predictive. As expected, health training made the strongest unique contribution to explaining health literacy skill level when all other variables were controlled for ($\beta = .328$, $p \leq .001$). However, it is significant that within the culture of universal access existing in the military, once training was taken into account, neither age, education level, pay grade/rank, gender, and marital status made a statistically significant unique contribution to the prediction of health literacy. Instead, only race/ethnicity with African American as the reference category was identified as a significant predictor of health literacy ($\beta = .285$, $p \leq .001$).

The result on race/ethnicity is consistent with the Federal government's health policy position that non-White/non-Hispanics, particularly African Americans, suffer disproportionately from lower health literacy (HHS, 2000b). The result is also consistent with the recent findings from the 2003 NAAL. Moreover, this study's finding with regard to African Americans suggests that even within a culture of universal access to care where access to information and services is equal, other noneconomic determinant(s) may account for disparities in health literacy. This is important because unless these noneconomic determinant(s) are identified and addressed, it will be difficult for health professionals to reduce limited health literacy and in turn, eliminate health disparities within the U.S. population, particularly among non-White/non-Hispanics (HHS, 2000b).

Study Limitations

Data were collected from a convenience sample of 155 participants such that individuals with actual or perceived lower literacy/health literacy skills may have opted not to participate in the study. Hence, the results of this study are limited in their generalizability. Also, since the study was conducted in a medical center, the positive impact of increased exposure to health information and services on health literacy skill level (even without health training) cannot be discounted. Finally, health literacy is a complex construct and difficult to define, much less measure. With only two main instruments available to measure health literacy (the S-TOFHLA and the REALM), the results of any study must take into account the limitations of either tool's ability to measure the construct of health literacy. Likewise, the results of the reliability and validity testing done in the study population were low to moderate and these findings should be taken into account when considering the results of this study.

Recommendations and Implications for Nursing and Future Research

The fact that even within a culture of universal access, African Americans still had lower health literacy than other racial/ethnic groups is an important finding for clinical nursing. Health care disparities between White/non-Hispanics and non-White populations have been found across a wide range of disease areas and clinical services. Disparities have also been found across a range of clinical health care settings. Improving health literacy is an essential tool for eliminating health disparities (HHS, 2000b). Thus, the findings in this study clearly support the need for nurses to conduct additional health literacy research in a variety of populations including populations with universal or near universal access to care.

In addition, when one considers that while 22% of variance in health literacy was accounted for in this military population by the study variables, another 78% is unaccounted for. Determining what noneconomic determinant(s) account for this unexplained variance and what clinical nursing practices would be effective in countering the negative impact of these determinant(s) should be topics of future research. As part of this effort, research aimed at developing additional tools to measure health literacy and assessing the psychometric properties of current tools in a variety of study populations is needed.

From a clinical standpoint, this study should also alert nurses to the fact that health literacy skill level may differ among their patient populations. This is especially important when providing patient education and counseling, regardless of whether patients have universal access to health care. Indeed, patients who receive health care within a culture of universal access like active-duty military members are still at risk for limited health literacy (IOM, 2004). Nurses should be cognizant of this risk and tailor their clinical practices accordingly. Similarly, from a health systems perspective, universal access to care does not mean that patients with such access are not at risk for limited health literacy. As the IOM pointed out in its report on health literacy, even within health systems that offer universal access to health care such as the MHS and Indian Health Service, there is still a need to develop programs to reduce the negative effects of limited health literacy, e.g., health disparities, overweight/obesity, higher costs (IOM, 2004).

References

Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. R. (1999). Development of a brief test to measure functional health literacy. *Patient Educ Couns, 38*(1), 33-42.

Davis, T. C., Long, S. W., Jackson, R. H., Mayeaux, E. J., George, R. B., Murphy, P. W., et al. (1993). Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Fam Med, 25*(6), 391-395.

Department of Defense (DoD) (2008). DoD Tricare Management Activity: Caring for America's Heroes: 2008 Stakeholder's Report. Retrieved from www.tricare.mil/stakeholders.

Department of Health and Human Services (HHS) (2000a). *Healthy People 2010: Objectives for improving health (Part A: focus areas 1-14.).* Retrieved from http://www.healthypeople.gov/Document/pdf/Volume1/11HealthCom.pdf.

Department of Health and Human Services (HHS) (2000b). *Healthy People 2010: Understanding and Improving Health.* Retrieved from http://www.healthypeople.gov/.

Department of Defense (DoD) Appropriations Bill (2007). P.L. 109-289. Availble at http://thomas.loc.gov/cgi-bin/query/D?c109:7:./temp/~c109CLYQQ7.

Dolan, N. C., Ferreira, M. R., Davis, T. C., Fitzgibbon, M. L., Rademaker, A., Liu, D., et al. (2004). Colorectal Cancer Screening Knowledge, Attitudes, and Beliefs Among Veterans: Does Literacy Make a Difference? *Journal of Clinical Oncology, 22*(13), 2617-2622.

Guilford, M., & Morgan, M. (2003). *Access to health care.* New York, NY: Routledge.

Hymann, J. J., Reid, B. C., Mongeau, S. W., & York, A. K. (2006). The military oral health care

    system as a model for elimination disparities in oral health. *Journal of Americal Dental*

    Association, 137, 372-378.

Institute of Medicine (IOM). (2004). *Health Literacy: A Prescription to End Confusion*

    (Bohlman, L.N., Panzer, A.M., Kind, D.A., eds). Institute of Medicine of the National

    Academies:Washington, D.C.: The National Academies Press.

Kirsch, I. S., Jungeblut, A., Jenkins, L., & Kolstad, A. (2002). *Adult Literacy in America: A*

    First Look at the Results of the National Adult Literacy Survey (3rd ed). Washington,

    D.C.: U.S. Department of Education: National Center for Education Statistics.

Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. (2006). *The Health Literacy of America's*

    Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006-483).

    U.S. Department of Education. Washington, DC: National Center for Education

    Statistics.

Tabachnick, B. G., & Fidell, L. S. (2001). *Using multivariate statistics* (4th ed.). New York: NY:

    HarpersCollins.

Table 1

Variables, Operational Definitions, and Study Measures

Variable	Operational Definition	Measure
Literacy	Estimated reading grade level in the health context	REALM
Health Literacy	Ability to read and understand the things they commonly encounter in the health care setting	S-TOFHLA
Health Context – Culture & Society in an active-duty military population	*Socio-demographic characteristics that impact the individual service member	Gender Age Rank/Pay grade Race/Ethnicity Marital Status Education level health professional training status (RN, medic, etc.) health care position Financial and structural access to care (MHS)

* A socio-demographic (SDC) collection sheet was used to collect self-reported data on gender, marital status, race/ethnicity, pay grade/rank, and whether the service member had health professional training, e.g., R.N., M.D., combat medic, or worked in a health care position.

Table 2

Summary of Demographic Characteristics

Characteristics	No. of Cases	Percent of Total
Age, mean years (SD) * (N = 153)		29.3 (8.08)
Less than 24 years	55	35.9
25-39 years	74	48.4
40-49 years	24	15.7
Gender (N = 155)		
Male	73	47.1
Female	82	52.9
Marital Status (N = 154)		
Single, never married	59	38.3
Married/Separated/Divorced/Widowed	95	61.7
Current pay grade/rank (N = 147)		
Enlisted personnel/noncommissioned officers	120	81.6
Officer personnel	27	18.4
Highest level of education (N = 155)		
GED/High School Diploma	33	21.3
More than High School Diploma	122	78.7
Race/Ethnicity (N = 155)		
African Americans	44	28.4
Other Race/Ethnicities	111	71.6

Characteristics	No. of Cases	Percent of Total
Has received health professional training (N = 55)		
Yes	60	38.7
No	95	61.3

*Not all respondents answered all questions on the SDC survey, so the "n" varies between

questions

Table 3

Summary of S-TOFHLA and REALM Scores

Study Variable	No. of Cases	Percent of Total
S-TOFHLA-numeracy (1-100 total score),		
Mean score (SD) 91.4-7.4	155	99.4
Median 93.0		99.4
Adequate health literacy (Score of 67-100)	154	
REALM, (1-66 total score)		
Mean score (SD) 64.5-2.8	152	
Median 65.0		
9th grade reading level or above	144	94.6
7th – 8th grade reading level or above	7	4.7
4th -6th grade reading level or above	1	.7

Table 4

Standard Regression of Sociodemographic Characteristics on Health Literacy

		df	F	p
Multiple R = .470				
R square = .221	Regression	7	5.556	0.000
	Residual	137		

Variable	B	SE	Beta	p value
Gender	-.793	1.159	-.055	.495
Age	.136	.083	.152	.104
Marital Status	-.704	1.271	-.047	.580
Level of Education	2.114	1.476	.120	.154
Pay grade/Rank	.611	1.531	.033	.690
Race/Ethnicity	4.565	1.255	.285	.000*
Health Training	4.853	1.180	.328	.000*

Note. The reference categories were: African Americans (versus all racial/ethnic groups);

females (versus males); officers (versus enlisted); training (versus no training); members with

high school or less (versus some college or more education).

*significant at $p \leq .05$.

Chapter 9. Dissertation Abstract

ABSTRACT: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel at a Major Medical Center

Background. Research in the national population has revealed a link between limited health literacy and disparities in health care utilization and resulting health status. Limited health literacy has also been found at higher rates among individuals who are non-whites, have lower education levels and/or income, and may differ by gender. In the military health system (MHS), gender, race, educational level and income should not impact the availability of health services as all active-duty personnel have universal access to health care. Yet disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Limited health literacy may be contributing to these disparities in active duty military personnel with universal access to health care, services, and information. To date, there are no published research studies assessing health literacy in the active-duty military population. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the national population.

Objective. The purpose of this study was to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of the national population to those of the active duty military.

Design. Using a descriptive design guided by the Health Literacy Framework, as adapted, this study conducted preliminary step in testing the hypothesis that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, and race/ethnicity. The designed allowed for the identification and description of estimated reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy and gender, rank, and race/ethnicity. Identification and description was assessed using the Rapid Estimate of Adult literacy in Medicine (REALM) and short version of the Test of Functional Health Literacy in Adults (S-TOFHLA) which are the two most widely accepted instruments for measuring health literacy. The study's design also provided a platform for evaluating the practicality of using the S-TOFHLA in a sample of active duty military personnel.

Methods. A convenience sample of 155 subjects was recruited at Walter Reed Army Medical Center (WRAMC) from January 2007 to May 2007. Average scores derived from the S-TOFHLA were compared across sociodemographic subgroups using a two group (independent) samples t-test, one-way analysis of variance (ANOVA), and linear regression.

Results: Ninety-nine percent of the sample was found to have adequate health literacy skills. Significant differences were noted for health professional training (p = .000). S-TOFHLA scores were also significantly different by race/ethnicity [F(3, 43)= 5.7, p =.002 with specific post-hoc comparisons revealing a difference between African Americans and White subgroups (p = .000). Health training and being African American were the only significant SDC predictors of health literacy skill level (p = .000). Additionally, the S-TOFHLA was found to be a practical and tool for measuring health literacy skills in a busy clinic area.

Implications: Compared to the national population, the overall health literacy rates of the military subjects are higher. However, a significant difference between Whites and African-Americans within a culture of universal access to care suggests that other non-economic determinant(s) may influence health literacy skill level. Closing the gap in health literacy among racial/ethnic groups is essential to reducing health disparities occurring at varying levels of access. Results support the need for additional health literacy research. Nurses should consider variations in health literacy skill level by SDC when providing care.

Chapter 10. Dissertation Defense

An Assessment of Health Literacy Rates in a Sample of Active-Duty Military Personnel

Konstantine Keian Weld, CAPT, USPHS
Uniformed Services University
July 21, 2008

Key players

- Dissertation Committee
  - Chair
    - Sandra Bibb, DNSc, RN, (CAPT) ret., USN, NC
  - Members
    - Diane Padden, Ph.D., CRNP
    - Gloria Ramsey, J.D., R.N.
- Acknowledgements
  - Cara Olsen, Ph.D.
  - COL Richard Ricciardi, Ph.D., CRNP, FAANP
  - WRAMC, Ward 73 staff and Army Nurse Corps
  - OPHS, ASH, and PHS Chief Nurse

2

BACKGROUND

■ 1/3 of the United States population suffers from limited health literacy (LHL)

■ LHL linked to overweight/obesity, lower use of preventive services, poorer health status

■ Higher rates of LHL associated with non-Whites, lower education levels and/or incomes, and gender (males)

3

Federal/Military Significance

■ Improving LHL is essential to eliminating health disparities

■ Disparities continue to exist in the military even within a culture of universal access to care

■ Improving health literacy may decrease costs, improve health status, and eliminate health disparities -- May improve <u>force readiness</u>

4

Universal Access

■ Exists when financial access and structural access are present and there are no known real or perceived barriers to health care

■ There may only be "near" universal access at the individual level due to personal barriers to receiving or obtaining health care

5

Specific Aims

■ Identify the literacy skills and health literacy skills in a sample of active-duty military personnel

■ Examine the relationship between LHL and sociodemographic characteristics (SDCs) (gender, race/ethnicity, rank, age, education level, marital status, and health training)

■ Evaluate the reliability, validity, and practicality of the Short – Test of Functional Health Literacy in Adults (S-TOFHLA)

6

Figure 1.

Health Literacy Framework – Universal Access (with military focus)
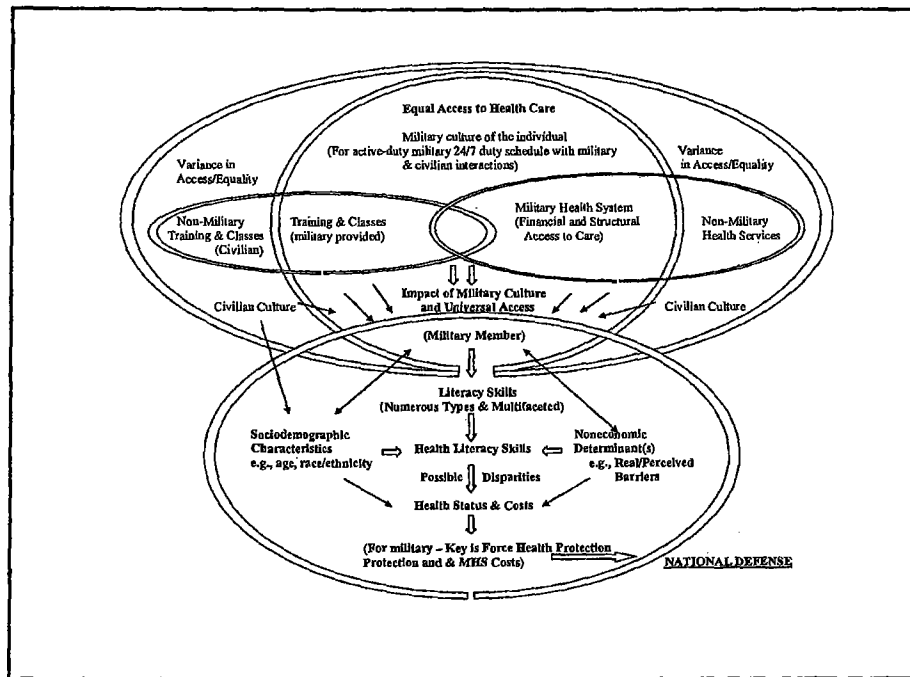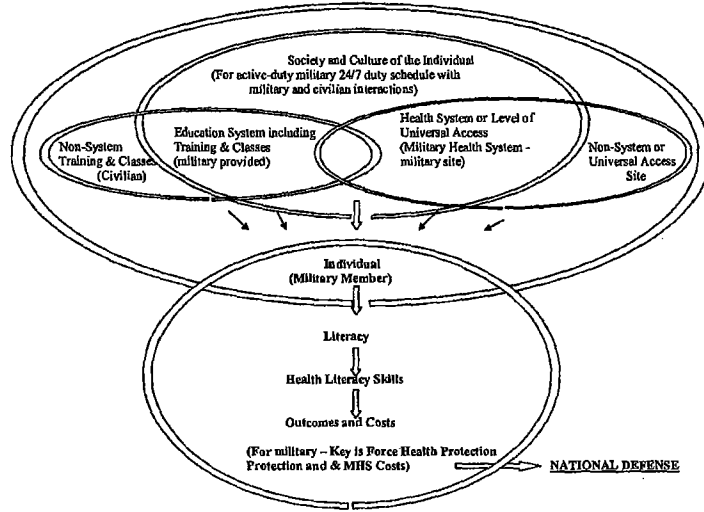
Methods

- Site: Walter Reed Army Medical Center, Family and Internal Medicine Clinic

- Convenience sample of 155 participants

- Demographic questionnaire: gender, age, education level, pay grade/rank, marital status, race/ethnicity, health training

- S-TOFHLA and Rapid Estimate of Adult Literacy in Medicine (REALM) were two instruments used in study

- Written consent and HIPAA acknowledgement obtained

9

Identify literacy/health literacy skills

- Test: S-TOFHLA and REALM

- REALM = 95% of participants had estimated reading grade levels at the 9th grade level or higher

- S-TOFHLA = 99% of participants were found to have adequate health literacy skills

10

Examine the relationship between LHL and SDCs

- Independent Sample t-test, ANOVA, Standard Linear Regression

- t-test showed significant difference between those with health training (M = 94.47, SD = 5.02) than those without training (M = 89.41; SD = 7.75) at t(153) = 4.49; p < .001

11

One-Way ANOVA for S-TOFHLA based on Race/Ethnicity

Category	Sample Size	M	SD
White/non-Hispanic	78	93.4103	5.14071
African American	44	87.7727	9.06787
Hispanic	17	91.5294	6.92024
Other	8	88.1250	7.84561

Source	Sum of squares	df	MS	F	P
Between Groups	975.325	3	325.108	6.689	.000
Within Groups	6767.709	143	47.327		

6

Standard Linear Regression of Sociodemographic Characteristics on Health Literacy (S-TOFHLA)

Multiple R	= .470		df	F	p
R square	= .221	Regression	7(137)	5.556	0.000

Variable	B	SE	Beta	p value
Gender	-.793	1.159	-.055	.495
Age	.136	.083	.152	.104
Marital Status	-.704	1.271	-.047	.580
Level of Education	2.114	1.476	.120	.154
Pay grade/Rank	.611	1.531	.033	.690
Race/Ethnicity	4.565	1.255	.285	.000*
Health Training	4.853	1.180	.328	.000*

*significant at p < .05

Reliability, Validity, Practicality of the STOFHLA

- Cronbach's alpha: S-TOFHLA's 4 numeracy items was low at .38, but moderately reliable at .70 for the 36 Cloze items

- The association between the S-TOFHLA and the REALM was low at r=.10 (N = 155, p <.05)

- Efficient tool to use in high-temp clinic area

14

7

Limitations

- Convenience sample drawn from health care environment and some participants had health training

- Only two main instruments available to test health literacy

- Internal consistency and reliability were low

16

Conclusions/Implications

- Health literacy rates were encouraging

- Sociodemographic predictors of health literacy: health training (anticipated) & race/ethnicity (unanticipated)

16

Conclusions/Implications

- Even within a culture of universal access, a significant difference in health literacy scores between Whites and African-Americans suggests that other noneconomic determinant(s) may influence health literacy

- Need for additional research and implications for clinical nursing practice

17

THANK YOU FOR YOUR ATTENTION!

QUESTIONS?

18

Uniformed Services University of the Health Sciences
Graduate School of Nursing
Report of Dissertation Defense for the
Doctor of Philosophy Degree (Form H$_A$)

Title of the dissertation: ___An Assessment of Health Literacy Rates in a Sample of Active-Duty Military Personnel at a Major Medical Center___

The decision of the Dissertation Committee is:

PASS
A. Both the dissertation and the oral defense are satisfactory: ___X___ / ScB

B. Minor changes are recommended by the Dissertation Advisory Committee that are to be made to the satisfaction of the Dissertation Chairperson: _____

DEFER
A. Major changes in the dissertation are required. Changes must be made to the satisfaction of the Dissertation Chairperson: _____

B. Major changes in the dissertation are required. Changes must be made to the satisfaction of the Dissertation Advisory Committee and at that time the oral defense will be rescheduled: _____

FAIL
Neither the oral performance nor the dissertation are adequate: _____

Signatures of the Committee
Chairperson: _Sandra C. BSS 7/21/08_

Member: _Diane Padden 7/21/08_

Member: _Gloria Ramsey 7/21/08_

Member: _____

Approval/Disapproval
Signature: _____   Date: _7/21/08_
Director, Doctoral Program

Approval/Disapproval
Signature: _____   Date: _7-21-08_
Dean, Graduate School of Nursing, USUHS

Form H$_A$: Applicable to PhD Students Records from Inaugural to 2006 Entry Class
Supports Doctoral Handbook Policies Prior to the 2007 Handbook

Certification of Dissertation (Form I)

Name of Student: _Konstantine Keian Weld_

This is to certify that the accompanying copies of the doctoral dissertation of the student named above are completed and correct copies as approved by the Dissertation Advisory Committee.

Title of the dissertation: _An Assessment of Health Literacy Rates in A Sample of Active Duty Military Personnel at a Major Medical Center_

Sandra C. Bibb   _Sandra C. Bibb_   _7/21/08_

Signature, Chairperson	Printed Name	Date

(Approval/Disapproval)

Signature: _____   Date: _7-21-08_
Director, Doctoral Program

(Approval/Disapproval)

Signature: _____   Date: _7-21-08_
Dean, Graduate School of Nursing, USUHS

APPENDICES A-E

Appendix A.

Uniformed Services University of the Health Sciences
Notice of Intramural Funding

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
F. EDWARD HEBERT SCHOOL OF MEDICINE
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799

Notice of Fund Approval
Change Number: Original

Project Number: T061IR-01
Principal Investigator: Konstantine Kelan Weld
Department: GSN-Graduate School of Nursing
Sponsor: Uniformed Services University of the Health Sciences
Project Type: USUHS/Graduate Student
Title: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel

Project Period: 01/11/2008 - 09/30/2008
Budget Period: 01/11/2008 - 09/30/2008

Budget Category	Budgeted Amount
Personnel:	$0
Travel:	$0
Supplies/Other Expenses:	$2,500
Equipment:	$0
Grants/Stipends:	$0
Support Cost Recovery:	$0
Total:	$2,500

Remarks:
Funding is contingent upon the availability of funds.

This Notice of Fund Approval represents your award in the amount of $2,500 loaded in the supply/other category. All Funds must be spent by September 30, 2008. Upon completion of this project, a final progress report must be submitted to the Office of Research.

Questions regarding this award should be directed to Sharon McIver at 301- 295-9814 in the Office of Research.

Mary Kay Gibbons 1/11/08
for Toya V. Randolph, PhD, MSPH
Director, Research Development Office
Uniformed Services University of the Health Sciences

Date Funding Accomplished: _1/14/2008_   Budget Officer: _Verna M. Hill_

cc: Shohreh Razi
    Mary Kay Gibbons
    Sandra Garmon-Bibb

Appendix B.

Form L: Verification of Completion of Qualifying Examination

Uniformed Services University of the Health Sciences
Graduate School of Nursing
PhD Program
Verification of Completion of
Qualifying Examination
Form L

<u>Verification of Submission of Qualifying Examination</u>

Date: ___22 MAY 2006___

Dissertation Chairperson: ___Sandra C. B___ Date: ___7/11/08___

<u>Verification of PhD Student Passing Qualifying Examination</u>

Date: ___22 May 2006___

Dissertation Chairperson: ___Sandra C. B___ Date: ___7/11/06___

(The verifications above can be notification by
Email or Other Written Communication)

<u>Verification of Successful Completion of Qualifying Examination</u>

Attach Policy Statement from Appropriate Class Year in Handbook Regarding
Requirement of Passing Grade on Qualifying Examination
Prior to Dissertation Proposal Defense

Form E: Report of Proposal Defense Examination To Be Attached

Form L: Applicable to PhD Students Records from Inaugural to 2006 Entry Class
Supports Doctoral Handbook Policies Prior to the 2007 Handbook

Appendix C.

Abstract Submission

Health Literacy Rates in a Sample of Active-Duty Military Personnel

(Konstantine Keian Weld, CAPT, USPHS, Richard Ricciardi, COL, AN, Sandra G. Bibb, CAPT, USN (ret))

Objective: To describe the relationship between sociodemographic characteristics (SDCs) (gender, race/ethnicity, education level, marital status, pay grade/rank, health professional training) and health literacy in a sample of active-duty military personnel using the shortened Test of Functional Health Literacy in Adults (S–TOFHLA).

Framework: The study was guided by the Health Literacy Framework.

Design and Methods: A convenience sample of 155 subjects was recruited at a major military medical center from January 2007 to May 2007. Average scores derived from the S-TOFHLA were compared across SDC subgroups using a two group (independent) samples t-test and one-way analysis of variance (ANOVA).

Results: Ninety-nine percent of the sample was found to have adequate health literacy skills. Significant differences were noted for health professional training ($p = .000$). S-TOFHLA scores were also significantly different by race/ethnicity [$F(3, 43) = 5.7$, $p = .002$ with specific post-hoc comparisons revealing a difference between African Americans and White subgroups ($p = .000$).

Implications: Compared to the national population, the overall health literacy rates of the military subjects are higher. However, a significant difference between Whites and African-Americans within the military where economic access to care is equal, suggests that other non-economic determinant(s) may influence health literacy skill level. Results support the need for additional health literacy research. Nurses should consider variations in health literacy skill level by SDC when providing care.

Objectives:

1. Define the concept of health literacy.

2. Describe the health literacy skill level in a sample of active-duty military personnel.

3. Describe how the Health Literacy Framework can guide health literacy research and clinical nursing practice.

2008 Karen A. Rieder Research/Federal Nursing Poster Session

Thank you for your poster submission.

For those of you who do have something to diclose, Maria Burcroff will send you the CE Disclosure Form with instructions.

For any questions or concerns, please contact:
Maria Burcroff
Fax: 301-295-7052
Email: mburcroff@usuhs.mil

You will be notified by August 15, 2008 of the status of your submission.

Appendix D.

Acknowledgement for Participation as Committee Member for Masters of Nursing
Students Health Literacy Project. Citation: Norwood, R.M. and Meyer, J.F., Factors
Associated with Health Care Professionals" Choice of Written Asthma Management
Plans, *Military Medicine*, 172, 10:1058, 2007.

Appendix E.

Institutional Review Board Protocols for
Walter Reed Army Medical Center
and Uniformed Services University of the Health Sciences

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON DC 20307-5001

REPLY TO
ATTENTION OF

MCHL-CI   24 October 2007

MEMORANDUM FOR COL Richard Ricciardi, AN, Chief, Nursing Research Service, Department of Nursing, Walter Reed Army Medical Center, Washington, DC 20307-5001

SUBJECT: Approval to Begin Protocol **Work Unit # 07-75039**: New Title: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel at a Major Medical Center

1. Congratulations! Your protocol was approved with revisions, by expedited procedure, at the Clinical Investigation Committee (CIC) on 18 September 2007 as a "minimal risk" human use protocol and was reported to the Human Use Committee (HUC) on 10 October 2007 with a change in the title of the study. Final required revisions were received on 24 October 2007. Please use the assigned seven (7) digit **Work Unit # 07-75039** for all correspondence with the Department of Clinical Investigation (DCI) regarding this study as noted on item 4 below.

2. A copy of the minutes from the applicable committee(s) and a final copy of the approved research protocol are attached for your administrative files. **Also, enclosed is the approved stamped consent form that must be duplicated and used for enrolling subjects, and the "STEP-BY-STEP GUIDE..." to be used when consenting subjects.** You may begin work on the project upon receipt of this letter. Your research protocol was approved for the consenting of up to 200 subjects at Walter Reed. This approval is only for one year. As part of your continuing review and re-approval and in order to keep your research ongoing, you are required to submit an annual progress report (APR) in the first week of **August** each year.

3. No funding is required nor approved from DCI.

4. As the principal investigator (PI), you are required by Federal, DoD, and WRAMC regulations to submit the following in a timely fashion to the Department of Clinical Investigation if applicable: (a) addenda delineating any changes in the protocol, (b) PI change, (c) notification of serious or unexpected adverse effects within 24 hours, and (d) publication clearance, travel orders, and funding requests.

5. **Also enclosed, is a copy of the NARMC DoD Multiple Project Assurance (MPA) and the WRAMC Federal-Wide Assurance (FWA) that all investigators agree to adhere to in conducting research, as attested to by your submission of a signed Principal Investigator Responsibilities Statement.** If you have any questions, the POC is Ms. Verna Parchment at (202) 782-7828.

Encls
as
MARY M. KLOTE
MAJ, MC
Chief, Research Review Service
Asst. Chief, Department of Clinical Investigation

CF: Research Administration Service

FINAL COPY

1

) .   **MCHL-NRS**   **DATE: 24 October 2007**

MEMORANDUM FOR CHIEF, DEPARTMENT OF CLINICAL INVESTIGATION, WALTER REED ARMY MEDICAL CENTER

SUBJECT: Application and Request for Approval of Clinical Investigation Study Proposal

1. PROTOCOL TITLE:

Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel at a Major Medical Center

2. PRINCIPAL INVESTIGATOR:

COL Richard Ricciardi, AN
Chief, Nursing Research Service
Department of Nursing
Phone: 202-782-7025
Fax: 202-782-5058
Current Duty Station: Walter Reed Army Medical Center
Research Course Training Date: 03/16/07

3. ASSOCIATE INVESTIGATORS:

CAPT Konstantine Keian Weld, U.S. Public Health Service (USPHS)
Doctoral Student Uniformed Service University of the Health Sciences (USUHS)
Phone: 240-638-6075/240-453-6080 or 6084
Fax: 240-453-6109
Research Course Training Date: 10/23/07

4. COLLABORATING PERSONNEL:

Not Applicable

5. MEDICAL MONITOR:

Not Applicable

6. ABSTRACT:

Research in the national population has revealed a link between limited health literacy and disparities in health care utilization and resulting health status. Limited health literacy has also been found at higher rates among individuals who are non-Caucasian, have lower education levels and/or income, and may differ by gender. In the military health system (MHS), gender, race, educational level and income should not impact the availability of health services as all active-duty personnel have universal access to health care. Yet, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Limited

MCHL-NRS   **DATE: 24 October 2007**

MEMORANDUM FOR CHIEF, DEPARTMENT OF CLINICAL INVESTIGATION, WALTER REED ARMY MEDICAL CENTER

SUBJECT: Application and Request for Approval of Clinical Investigation Study Proposal

1. **PROTOCOL TITLE:**

Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel at a Major Medical Center

2. **PRINCIPAL INVESTIGATOR:**

COL Richard Ricciardi, AN
Chief, Nursing Research Service
Department of Nursing
Phone: 202-782-7025
Fax: 202-782-5058
Current Duty Station: Walter Reed Army Medical Center
Research Course Training Date: 03/16/07

3. **ASSOCIATE INVESTIGATORS:**

CAPT Konstantine Keian Weld, U.S. Public Health Service (USPHS)
Doctoral Student Uniformed Service University of the Health Sciences (USUHS)
Phone: 240-638-6075/240-453-6080 or 6084
Fax: 240-453-6109
Research Course Training Date: 10/23/07

4. **COLLABORATING PERSONNEL:**

Not Applicable

5. **MEDICAL MONITOR:**

Not Applicable

6. **ABSTRACT:**

Research in the national population has revealed a link between limited health literacy and disparities in health care utilization and resulting health status. Limited health literacy has also been found at higher rates among individuals who are non-Caucasian, have lower education levels and/or income, and may differ by gender. In the military health system (MHS), gender, race, educational level and income should not impact the availability of health services as all active-duty personnel have universal access to health care. Yet, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Limited

health literacy may be contributing to these disparities in active duty military personnel with universal access to health care, services and information. To date, there are no published research studies assessing health literacy in the active-duty military population. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the national population. The purpose of this study is to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of the national population to those of active duty military. Using a descriptive design guided by the Health Literacy Framework, this study will conduct preliminary steps in testing the hypothesis that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, and race/ethnicity. The design will guide the identification and description of estimated reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy skills and gender, rank, Service, and race/ethnicity. This identification and description will be assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM) and short version the Test of Functional health literacy in Adults (S-TOFHLA) which are the two most widely accepted instruments for measuring health literacy. The study's design will also provide a platform for evaluating the reliability, validity and practicality of using the S-TOFHLA in a sample of active duty military personnel. The target population for this study is active-duty military personnel while data will be collected from the accessible population which is active-duty military personnel who are permanent staff, visiting, and/or being treated at WRAMC.

7. OBJECTIVES:

The long-term goal of this study is to explore the relationship between limited health literacy, health care utilization, and improved health status and outcomes. It is hypothesized that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, age, race/ethnicity, and marital status.

The two primary and one secondary specific aims of this study are:

1. To identify the literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional Health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

2. To examine the relationship between limited health literacy skills and gender, race/ethnicity, pay grade/rank, age, education level, and marital status in a sample of active-duty military personnel.

3. A secondary aim of this study is to evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

8. MEDICAL APPLICATION:

If the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, age, race/ethnicity, and marital status (research hypothesis), then universal access to care and services within the MHS might not be enough to overcome disparities in health care utilization, health status, and health outcomes. New policies and targeted patient/health education strategies may need to be developed and/or

implemented to improve health literacy within the active-duty population, before targeted goals for improving health status and increasing use of preventive services can be accomplished. Accordingly, the results of this preliminary study are significant for the Federal government/military because:

1. Health literacy research has not been conducted in the active-duty military population although limited health literacy has been identified as a national health problem by the Federal government and the Institute of Medicine (IOM) has recommended that Department of Defense (DoD) should focus on the issue of limited health literacy and seek ways to reduce its negative impact within the Military Health System; and

2. Limited health literacy is related to poorer health status, lower use of preventive services, and overweight/obesity which in the military can lead to a reduction in individual, unit and operational readiness, e.g., loss duty time, less fit force, as well as increased inpatient health care costs when resources are limited due to wartime pressures.

9. BACKGROUND AND SIGNIFICANCE:

At least one-third of the population lacks the health literacy skills to effectively use their respective health system. Results from the recent 2003 National Assessment of Adult Literacy (NAAL) indicate that on a 4-level scale ranging from below-basic to proficient health literacy, only 25 million adults in the United States have proficient health literacy while 75-million adults have health literacy skills at the basic or below basic level (Kutner, 2006). Literacy is the ability to read and write or knowledge of a particular subject (Dictionary.Com, 2006). Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (Selden, Zorn, Ratzan, & Parker, 2000)." Achieving proficient health literacy depends upon individual ability, the suitability of the health information from a health literacy perspective, and/or both.

Limited health literacy has been linked to higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited health literacy have also been also been linked to individuals who are non-Caucasian, have a lower education level, and/or income, and may differ by gender [Institute of Medicine (IOM) 2004; Kutner, 2006].

In the active-duty military population, the extent of limited health literacy is unknown and no surveys and/or research was found in Cumulative Index to Nursing & Allied Health Literature (CINAHL) and Pubmed databases involving military personnel. The IOM has however, identified military recruits as a population known to have limited literacy skills and thus, suspected of having limited health literacy skills. Because of this and the concern that other military members may lack proficient health literacy skills, the IOM has also recommended that DoD develop and support programs that will effectively reduce the negative impact of limited health literacy and consider exploring ways to make health materials more appropriate and user friendly (IOM, 2004).

The concept of "health literacy" was first identified in a 1974 paper titled Health Education as Social Policy (Selden et al., 2000; Simonds, 1974). In the 1974 paper, Simonds discussed the link between health literacy and health education and called for minimum standards for "health literacy" for all school grade levels. Since that time, the concept of health literacy has been defined in numerous ways with varying emphasis on the skill sets required for health literacy and personal empowerment. The most common definition of health literacy used by the scientific and clinical practice communities is the one developed for a study by the National Library of Medicine (NLM) literacy to aid in debate over how to define health literacy and advance health literacy programs (Selden et al., 2000). For the NLM study, health literacy was viewed from a skills-based perspective

and health literacy was defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Selden et al., 2000). This conceptual definition has been adopted by the IOM and Healthy People 2010 (HHS, 2000) and the majority of the 3500 citations in the NLM bibliography, "Health Literacy," (Selden et al., 2000) and 651 citations in the NLM bibliography "Understanding Health Literacy and its Barriers," (Zorn, Allen, & Horowitz, 2004), rely upon this definition (Tones, 2002).

When the 1992 National Adult Literacy Survey (NALS) was conducted, the nationwide survey found that about 90 million U.S. adults (out of 191 million or 47%) could not accurately and consistently locate, match, and integrate information from newspapers, advertisements, or forms (Kirsch, Jungeblut, Jenkins, & Kolstad, 2002). While these adults could perform a variety of straightforward tasks using printed material, they were unlikely to be able to perform, with accuracy and consistency, more challenging tasks using long or dense texts. This means that in 1992, almost half of the nationwide adult population had basic deficiencies in reading and computational skills or literacy skills that were inadequate for the many tasks needed to function successfully in the economy – including the health care economy (Parker, 2000). Moreover, of these adults, 40 million were found to be functionally illiterate with the remaining adults having only marginal literacy skills (Parker, 2000). In 2004, Rudd, Kirsch and Yamamoto created a five level health activities literacy scale (HALS) (like the 1992 literacy scale) and re-analyzed the 1992 NALS results with a focus on health related tasks. An estimated 23 million adults were found to perform health-related tasks at the lowest of five levels and 46 percent of adults performed in the bottom two levels (IOM, 2004; Rudd, Kirsch, & Yamamoto, 2004).

Results from the 2003 National Assessment of Adult Literacy (NAAL) which contained the first national assessment of health literacy are consistent with the 1992 NALS results and the Rudd, Kirsch, and Yamamoto (2004) re-analysis. The 2003 NAAL results indicate that on a scale ranging from below basic to proficient health literacy, a majority of the adults in the United States had only intermediate health literacy and 75-million adults had health literacy skills at the basic or below basic level. When these 75+ million adults encounter the health care system, they are likely to have difficulty with routine reading requirements, such as reading prescription bottles, food labels, appointment slips, self-care instructions, and health education brochures (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

Health literacy is now recognized as an important aspect of health promotion and disease prevention and critical to improving the health of our Nation and its citizens. In the military, limited health literacy may be contributing to disparities in health care utilization and improved health status even though active-duty military personnel have universal access to health care, services and information. Consider, in the context of the culture of the military health system (MHS), gender, race, educational level and income should not impact the availability of health services. The degree to which active duty military personnel are able to obtain health information and services needed to make appropriate health decisions, and improve health status is equal. All active-duty personnel have universal access to health care, and yet, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Although the percentage of military personnel classified as obese (Body Mass Index greater than 30.0) is low compared to the U.S. civilian population (12.4% vs. 31%), military personnel have shown a steady and statistically significant increase in obesity over the past 10 years (up from 8.6% in 2002 to 12.4%) (DoDHA, 2006). Hospitalizations for non battle injuries remain high relative to the Healthy People 2000 objective of 754 injuries per 100,000 ((Total DoD 2635/2679 for 2002/2005 and note that Healthy People 2010 does not specify objective rate and civilian estimates were not reported). Even with universal access to care, rates of overweight/obesity and hospitalization lag behind health improvement goals set in Healthy People 2010 (& 2000 for hospitalizations); and even, within a culture that emphasizes health promotion and disease prevention, military personnel do not currently

meet health promotion objectives in such areas as blood pressure checks (81.8% vs. 95% objective) and cholesterol checks (57.2% vs. 80% objective).

In summary, to date however, there are no published research studies assessing health literacy in the active-duty military population. Little is known about the degree to which active duty personnel have the capacity to process and understand basic health information, and the subsequent impact of this capacity on health care utilization and improved health status and outcomes. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the non-military population. The purpose of this study is to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of non-military populations to those of active duty military.

Specific Aim 1: To identify the literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

The two most widely accepted instruments for measuring health literacy are the Test of Functional health Literary in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM). The shortened version of the S-TOFHLA and the REALM will be used in this study.

The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages for a total of 36 Cloze items (comprehension skills measured). The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The S-TOFHLA has been shown to have good internal consistency (reliability) (cronbrach's alpha = .68 [4 numeracy items] and .97 [36 Cloze items] for reading comprehension) and concurrent validity compared to the long version of the TOFHLA (r=.91) and the REALM (r=.80). It takes 8-12 minutes to administer (See Attachment A for copy of S-TOFHLA which is selected portions of full test, development article on S-TOFHLA, and Attachment C for information sheet on instruments).

Unlike the S-TOFHLA which measures comprehension (ability to read and understand numbers), the REALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects are asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes by personnel with minimal training and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Attachment B for copy of REALM and Attachment C for information sheet on instruments). The criterion validity for the REALM has been established through correlation with other standardized reading tests at p <0.0001: Pearson Oral Reading Test-Revised (.97); Slosson Oral Reading Test-Revised (.96); and Wide Range Achievement Test (WRAT) reading subtest (WRAT-R) (.88). The REALM has good reliability (test-retest .99) and inter-rater (.99) and as indicated above, is highly correlated with the S-TOFHLA (r=.80). While the S-TOFHLA and REALM have not been used in an active-duty military sample, the instruments have been successfully used in a variety of civilian populations to measure health literacy. Nevertheless, the lack of previous testing in the military and results of the third specific aim should be factors to consider when interpreting the results of this preliminary study.

While the extent of literacy/health literacy has been assessed through the 1992 NALS, 2004 NALS/1992 re-analysis, and the 2003 NAAL (75-million adults with lowest two levels of health literacy skills), these national surveys did not use the TOFHLA or REALM. A review of the literature however, reveals that at least 20 research studies have used the TOFHLA, S-TOFHLA, or REALM to measure the extent of health literacy in civilian populations. These studies show that limited health literacy skills are common with significant variations in prevalence depending upon the setting and population sampled (IOM, 2004; Williams et al , 1995; Williams, et al., 1998), e.g., racial or ethnic status, general medical, HIV. These studies also suggest that segments of the U.S. population that could be considered at greatest risk for limited health literacy are those that were reported to have higher rates of limited literacy in the 1992 NALS (IOM, (2004)) and 2003 NAAL – minorities and lower income individuals.

As indicated above, health literacy skills have not been measured in the active-duty military population even though segments of the population have been identified by IOM (2004) as at risk for limited health literacy such a military recruits. Based on the sociodemographic characteristics (SDC) used in health literacy research with the national population, other segments of the active-duty military population are also at risk of limited health literacy skills, e.g., non Caucasian, and lower ranking personnel. Hence, it is critically important to asses the extent of health literacy in the active-duty population.

Specific Aim 2: To examine relationship between limited health literacy skills and gender, race/ethnicity, age, pay grade/rank, education level, and marital status in a sample of active-duty military personnel.

In addition to the national literacy/health literacy surveys, studies using the TOFHLA, S-TOFHLA and REALM have reported a link between limited health literacy and gender, higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited health literacy have also been also been linked to SDCs such as being non Caucasian, lower education, and/or lower income (IOM (2004), but as indicated above, non of these linkages have been studied in an active-duty military population.

The SDCs variables of gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) were chosen for this preliminary study because they represent points of comparison between the military and national population (See SDC data collection sheet at Appendix J).

As for specific examples in the literature suggesting a link between limited health literacy and the aforementioned variables in the national population, there are several. For example, in a study by (Arnold et al., 2001) involving smoking status, reading level, and knowledge of tobacco effects in low-income pregnant women, there was an association between limited health literacy and race (African American). In addition, associations between limited health literacy skills and racial and ethnic status have been identified in studies involving: HIV/AIDs medication adherence (Kalichman et al., 2000); stage of prostate cancer at diagnosis (Bennett et al., 1998) and (Dewalt, Berkman, Sheridan, Lohr, & Pignone, 2004); mediating effects of literacy on race; poorer diabetic outcomes (Schillinger et al., 2002) and cervical cancer screening practices (Lindau et al., 2002). A 2003 study found evidence that there were differences in health literacy status by race (African and Non-African Americans), but noted that much more research is needed because the results may be due to problems with the instrument or more general issues surrounding the assessment of education (Beers et al., 2003). In any event, the most important observation gleaned from the information presented above is the fact that the demographic groups identified in these studies are the same demographic groups identified as being at risk in the 1992 NALS and the reanalysis by Rudd, Kirsch, and Yamamoto (2004). However, as noted in the IOM (2004) health literacy report, none of the studies

identified in the field of health literacy thus far, have involved a sufficiently large random sample of adults to allow for full extrapolation to other populations. This preliminary study is an important step in understanding this phenomenon in the context of the active-duty military population.

Additionally, if relationships are found between gender, race/ethnicity, and rank and limited health literacy skills, analysis in this study will progress to the examination of the extent to which gender, race/ethnicity, and rank concepts predict the limited health literacy skills. Health literacy research studies in the national population have demonstrated a relationship between limited health literacy and gender, race/ethnicity, knowledge, health outcomes and socioeconomic status (Bennett et al., 1998; Dewalt et al., 2004; IOM, 2004; Kalichman et al., 2000; Lindau et al., 2002).

Specific Aim 3: To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

Like the TOFHLA, the S-TOFHLA was developed and has been used in the national population. To the researcher's knowledge, the S-TOFHLA has not been used in any published military research studies. The TOFHLA was developed in 1993 and found to be a valid, reliable indicator of patient's ability to read health-related materials (Parker, et al., 1995). Construct validity for the original TOFHLA was ensured by using actual hospital medical texts for both the reading comprehension and numeracy subtexts (Nurss, et al, 1995) while concurrent validity was shown by demonstrating statistically significant correlations between the REALM and the Wide Range Achievement Test-Revised (WRAT-R). The WRAT-R is an instrument that has three subtests which measure the codes which are needed to learn the basic skills of reading, spelling, and arithmetic (IOM, 2004). Correlations of the TOFHLA with the REALM and the WRAT-R were .84 and .74, respectively ($p<0.001$) by Spearman's rank correlation. The REALM and WRAT-R also have a significant correlation of .88 (Parker, et al., 1995).

The S-TOFHLA was developed and tested in 1997 in the same setting used for the development and testing of the TOFHLA – in a sample of 238 patient/subjects from an urban public hospital in Atlanta, Georgia. The results of the testing showed good internal consistency as reflected by a cronbach's alpha of .68 for the 4 numeracy items and .97 for the 36 Cloze items in the reading comprehension section. The correlation between the numeracy score and the reading comprehension score was .60 (Baker, et al., 1999; Williams, et al., 1995). The correlation between the S-TOFHLA and the REALM was .80 (Baker, et al., 1999; Parker, et al., 1995; Williams, et al., 1995). Correlations for subscores of the numeracy and Cloze sections were .61 and .81, respectively. All correlations were significant at $p<0.001$.

There were however, differences between the S-TOFHLA and the REALM in the mid-range of the tests in that the REALM appeared to overestimate and underestimate subject's reading ability when compared to the S-TOFHLA.. It was suspected that these differences might be due to the fact that some subjects were able to pronounce words correctly, but may still have poor reading comprehension while others may have difficulty pronouncing words in isolation (without the context of other materials on the S-TOFHLA) (Baker, et al., 1999). In any event, the development and testing of the S-TOFHLA provided a short instruments (8-12 minutes to administer) which can aid in the identification of patients who may require special efforts or new health materials to reach their health care goals. It is important therefore, to evaluate whether the instrument is a reliable, valid, and practical tool, e.g., ease and time of administration, for use in active duty military populations.

10. PLAN:

a. Investigational drugs/Devices status:

Not Applicable

b. Type and number of patients/charts/specimens to be studied:

Up to 200 subjects enrolled from active-duty personnel who are visiting, working at, or a patient at WRAMC. The use of 200 subjects is to ensure that the sample size is large enough to conduct the analysis being proposed for this study and to account for attrition.

c. Inclusion and exclusion criteria:

Inclusion Criteria:

1. Active duty personnel
2. Willingness to participate and able to read and understand English and answer a questionnaire

Exclusion Criteria:

1. Blindness
2. Speech impairment
3. Central Nervous System Disorders that effect reading and speaking
4. Unable to give consent

d. Recruitment:

Subjects will be recruited from active-duty military personnel who are staff, visitors, or patients at WRAMC using flyers and posters placed in the internal/family medicine clinics on Ward 73 at WRAMC (See advertisement at Attachment D). No compensation with be offered to subjects.

e. Consent process:

This study poses no more than minimal risk and does not collect any protected health information outside of the participant's name obtained on the consent and HIPAA forms. The associate investigator will meet with volunteers to obtain written informed consent, explain the study, and answer any questions regarding the concept of health literacy and the study. The dialogue between the investigator team and volunteer will take place in a private office area in WRAMC to ensure confidentiality.

f. Study design and methodology:

The overall research design for this study is descriptive prospective (Burns & Grove, 2005). The design will guide the identification and description of reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy skills and gender, rank and race/ethnicity. The design will also provide a platform for evaluating the reliability, validity and practicality of using the S-TOFHLA in a sample of active duty military personnel.

The purpose of this study is to conduct preliminary steps in testing the hypothesis that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, and race/ethnicity. Data will be collected at Walter Reed Army Medical Center (WRAMC). To address the potential for selection bias (participants that are in a health related work specialty), we will collect data on whether the participant works in health related field. The target population for this study is active-duty military personnel while the accessible population is active-duty military personnel (military personnel) who are permanent staff, visiting, and/or being treated at WRAMC. The overall research design for this is study is descriptive (Burns & Grove, 2005). The design will guide the identification and description of reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy skills and gender, rank and race/ethnicity. The design will also provide a platform for evaluating the reliability, validity and practicality of using the S-TOFHLA in a sample of active duty military personnel.

Consistent with the administration procedures used by researchers to develop the S-TOFHLA, visual acuity will be determined using a pocket vision screener but will not be recorded (Rosenbaum, Graham-Field Surgical Co., Inc. New Hyde Park, NY). Subjects with vision worse than 20/100 will be excluded unless corrected. Those with visual acuity between 20/70 and 20/100 will be given a large print (14 font) version of the S-TOFHLA. These impediments will be assessed through the interview process by the researcher. In addition, speech impairment will be assessed by researcher when discussing participation in the study with potential subject and blindness by observation of potential subject and questioning as to visual acuity – can they read letters of first word in REALM correctly.

The sociodemographic characteristics used in the second specific aim are based on relationships found in research on health literacy in the national population. The sociodemographic characteristics to be collected are gender, age, race/ethnicity, pay grade/rank, education level, marital status, and to provide context for data analysis, health professional status (Attachment E). The findings generated by this preliminary study will be used to: (1) gain a better understanding of health literacy in the active-duty military population; (2) provide information that may be useful in the development and/or revision of Federal agency/military policies and/or patient education materials, and (3) facilitate the development of hypotheses to guide future health literacy research.

Plan for each Specific Aim:

Specific Aim 1: To identify literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

Rationale: Even though the Federal government has noted that improvements in health literacy will improve health outcomes, better use of preventive services, and weight management and prevent obesity/overweight in the national population, there are no studies focused on health literacy in the active-duty military population. The first specific aim of this study is to describe health literacy skills among a sample of military personnel using the two most widely accepted instruments for measuring health literacy skills – S-TOFHLA and REALM. Comparative differences between males and females, White, non-Hispanics, & non-Whites and officers & enlisted will be assessed based on variations in health literacy skills that have been identified in health literacy research and national surveys to date. The S-TOFHLA (Attachment A) measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages – (comprehension skills measured) and can be administered in 8-12 minutes. The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health

literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The REALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects will be asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Attachment B).

Design and Procedures. The proposal is to be filed with the WRAMC/Department of Clinical Investigations Protocol Coordinator. Approval will be sought from the USUHS IRB as the associate principal investigator is a doctoral student in the USUHS/Graduate School of Nursing. After obtaining approval to conduct research at WRAMC and USUHS IRB approval, recruitment will be carried out by placing pamphlets and posters in the common area and clinics at WRAMC. A sample of the pamphlet and poster are included in this protocol for review and approval by the Department of Clinical Investigation (DCI) Protocol Coordinator. Upon approval, the pamphlet and poster will be submitted to the Executive Officer of WRAMC hospital for approval of content and placement with WRAMC.

Working under the guidance of the WRAMC principal investigator (PI), COL Richard Ricciardi, a private area/room will be identified in which subjects can receive information about the study and health literacy and be tested if they choose to do so voluntarily. Use of this room will ensure confidentiality, minimize outside distractions, and allow the researcher to provide information to subjects on the concept and importance of health literacy. For individuals agreeing to become subjects, the researcher will explain what the instruments are and how they are used. Upon providing informed consent , the following SDCs will then be collected along with health professional status: gender, age, marital status, race/ethnicity, and pay grade/rank (See Attachment E).

Data will be collected from a convenience sample of military members at WRAMC. Data will be analyzed to assess the extent of health literacy and to measure relationships between a subject's health literacy skill level and gender, race/ethnicity, marital status, and pay grade/rank.

Data results will be entered into a SPSS spreadsheet by the researcher. Results from the analysis will be used to complete doctoral studies and to facilitate the development of hypotheses to guide future health literacy research. Data will be stored according to WRAMC and USUHS rules and may be used in later research. Consistent with the IOM recommendation for DoD, the results may also provide information that may be useful in the development of effective policies and customized programs that address deficiencies in health literacy skills.

Problems and Solutions. It is estimated that the length of time required for each participant to complete the SDC data sheet, S-TOFHLA and REALM will be 20 minutes (8-12 minutes – S-TOFHLA/2-3 minutes - REALM, respectively). This time period may be too long for some military members to focus on the materials. The solution would be to drop the REALM for those subjects since the S-TOFHLA is the primary health literacy measurement and measures comprehension skills versus decoding skills by the REALM. The loss to the study would be inability to obtain reading grade level for that individual and a smaller sample size to evaluate the reliability, and validity of the S-TOFHLA.

Specific Aim 2: To examine the relationship between health literacy skills and gender, pay grade/rank, age, race/ethnicity, and education level in a sample of active duty personnel.

Rationale. In addition to the national literacy/health literacy surveys, studies using the TOFHLA, S-TOFHLA and REALM have reported a link between limited health literacy and gender, higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited

health literacy have also been linked to SDCs such as being non Caucasian, lower education, and/or lower income (IOM (2004), but as indicated above, none of these linkages (correlations and predictive relationships) have been studied in an active-duty military population.

The SDCs variables of gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) were chosen for this preliminary study because they represent points of comparison between the military and national population (See SDC data collection sheet at Attachment E). The rationale and instruments used to measure health literacy skills are the same as for the first specific aim.

Problems and Solutions. Same as indicated above in the first specific aim.

Table 1. Variables, Measures (Level of Data), and Analytic Approach

Variable Name	Nominal	Ordinal	Scale	Specific Aim(s) and Analytic Approach
Health Literacy	S-TOFHLA - Adequate & Inadequate (Marginal & Inadequate Combined using S-TOFHLA REALM -Adequate & Inadequate (Reading level <9th grade)	S-TOFHLA – 3 groupings -Inadequate -Marginal -Adequate REALM – 4 groupings -3rd and below -4th – 6th -7th – 8th -9th and above	S-TOFHLA -Score range = 1-100 REALM -Score range = 1-66	Aim 1 -Univariate statistics = measures of tendency, frequency distributions, categorical groupings of S-TOFHLA and REALM -Independent samples t test, ANOVA, Chi Square for comparing groups -Mann-Whitney, Phi & Fisher's Exact if appropriate for data to compare groups Aim 2 -Pearson's product moment correlation, Spearman's rank order correlation, and Chi Square to assess relationships Between SDCs (independent Variables (IVs) and test(s) (dependent Variables (DVs)) -Multiple linear regression and logistic regression, as appropriate Aim 3 -Cronbach's Alpha, Pearson's product Moment correlation, and Spearman's rank order correlation to assess reliability and validity of S-TOFHLA and REALM, respectively.
Sociodemographic Characteristics	Marital status ---Single, never married ---Married, living together ---Separated ---Widowed	Education -Did not graduate from high school -GED certificate -High School Diploma -Some college, but not 4-year college degree or higher	Age in years	Aim 1 -Univariate/Descriptive statistics -As IVs, the SDCs will be used to run independent samples t tests and ANOVAs with S-TOFHLA and REALM (as DVs) to compare groupings Aim 2 Same as Aim 2, above

Specific Aim 3. To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

Rationale. Health literacy skills have not been studied in the active-duty military population. The S-TOFHLA will be used to conduct this study along with the REALM. To assess whether the S-TOFHLA is an appropriate instrument for measuring health literacy skills in the military, the reliability, validity, and practicality of the instrument will be evaluated based on the data collected.
Problems and Solutions. Same as indicated above in the first specific aim.

Table 2. Timing Sequence:

Timeline	Oct 07	Nov 07	Dec 07	Jan 08	Feb 08	Mar 08	Apr 08	May 08	Jun 08	July 08	Aug 08	Sept 08	Oct 08	Nov 08				
Obtain IRB approvals	■	■																
Subject Recruitment			■	■	■	■												
Data Collection			■	■	■	■												
Data Analysis						■	■											
Dissemination									■	■	■	■	■					

Conceptual Framework

An extensive review of the literature reveals that numerous theories have been used to study the concept of health literacy. Doak, Doak and Root (1996) identified a number of these theories such as the health belief model, trans-theoretical model, social cognitive theory (SCT), and diffusion theory. None of these frameworks however, focus specifically on health literacy. Zarcodoolas, Pleasant, and Greer (2005) recently proposed a multi-dimensional health literacy model which focuses on four central literacy domains; fundamental, science, civic, and cultural. To date, this model has not used to guide published research.

Using the definition of health literacy formulated by the National Library of Medicine and used in Healthy People 2010, the IOM also developed a multi-dimensional health literacy model known simply as the Health Literacy Framework (HLF). The HLF focuses on the three sectors which assume responsibility for health literacy: culture and society, health system, and education system. These sectors provide intervention points for improving an individual's health literacy regardless of an individual's status and/or health system (IOM, 2004). This adaptability makes the HLF ideal for conducting health literacy research in the active-duty military population.

The HLF will be used to guide this preliminary study because as adapted, the HLF represents the theoretical interaction of military members with the three key sectors of health literacy and intervention points: educational systems, health care systems, and cultural/societal factors. Within this non-causal framework, literacy is the foundation for health literacy and provides the starting point for understanding and communicating health information and concerns. Health literacy is the bridge or active mediator(s) between military members and health contexts – situations and activities relating to health. Although associations between health literacy and health outcomes and costs have not been conclusively established, research findings suggest such a strong relationship between the concepts (IOM, 2004). As this is the first study on health literacy within the active-duty military population, this study will focus on the concepts of literacy and health literacy.

A visual depiction of the HLF is provided in Diagram 1, below. The diagram shows the essential framework for considering health literacy including the interaction(s) and relationship(s) between the three key sectors and intervention points for improving health literacy skills. Below this diagram, Table 3 sets forth a list of variable names, conceptual definitions, operational definitions, and corresponding measures, contained in the HLF

Diagram 1. Health Literacy Framework

Table 3. Health Literacy Framework, Variables, Definitions, and Applicable Measures

Variable Name	Conceptual Definition	Operational Definition	Measure
Literacy	Constellation of skills including reading, writing, basic , numeracy, & speech/speech comprehension in specific contexts [prose, document and quantitative] (Kirsch, 2001)	The grade reading level (or reading difficulty level)(literacy skills) - in the health context, the ability to read at the 10th grade level or above.	- REALM – Estimated Reading Grade Level
Health Literacy	Degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions	Subjects ability to read and under the things they commonly encounter in the health care setting	- S-TOFHLA - overall assessment of health literacy - REALM – decoding measurement of adult literacy in medicine for adults
Health Context (HC) & Intervention Points			
HC/IP – Culture & Society	Shared ideas, meanings, and values acquired by individuals as members of society. Includes social determinants of health such as native language, SDCs, along with influences of mass media and the plethora of health information sources available through electronic sources	SDCs - Gender, Marital Status, Race/Ethnicity, and Pay grade/ Rank plus health professional status	-Gender -Age -Rank/Pay grade -Race/Ethnicity -Marital Status -Education level -health professional train status (RN, medic, etc.) -Financial and structural access to care (MHS) -Deployed personnel -Policies mandating physical fitness

Table 3. Health Literacy Framework, Variables, Definitions, and Applicable Measures – Continued

HC/IP Health Syst	Refers to all people performing health related activities including those working in hospitals, clinics, offices, home health care, public health agencies, regulatory agencies, insurers,& accreditation groups	Military Health System – Program materials used in MHS and sample of military members who use MHS	Not being measured
HC/IP Education System	The education system in the United States 12), adult education programs and higher education along with formative and continuing education for health professionals	MHS patient education programs and health professional training including military Schools	Not being measured
Health Outcomes Costs)	Improvements in health status and/or cost savings but varies because contextual to person or health system being analyzed	Overweight/obesity, $$, knowledge of disease, healthy heart practices, and any other health outcome or monetary measurement	Not being measured

g. Serious and unexpected adverse events:

There are no expected risks or discomforts anticipated with this study. However, any serious and unexpected adverse events will be reported to the Human Use Committee in accordance with the Department of Clinical Investigation procedure.

The principal investigator (PI) will, within one working day, report any serious adverse events WRAMC to the Human Use Committee (HUC) by submitting an adverse event report memorandum to the HUC via DCI. Serious adverse events will be reported even if the PI believes that the adverse events are unrelated to the protocol.

Unexpected (but not serious) adverse events occurring in subjects enrolled at WRAMC which, in the opinion of the PI, are possibly related to participation in the protocol will be reported by the PI within 10 (ten) working days to the HUC using the same procedure.

h. Protocol Deviations:

Any protocol deviations during the course of the study will be reported promptly to DCI by submitting a protocol deviation memorandum to the HUC via DCI using the template on DCI web under filename deviation.doc.

i. Human Biological Specimens:
Not Applicable.

j. Patient confidentiality:

Your answers to the following questions will assist compliance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). The DoD HIPAA regulations 6025.LL-R and other guidance can be found on the DCI website.

i. Are you intending to collect data on any of the 18 personal health identifiers?

No – HIPAA does not apply – go to question #4

XXX Yes – please check which ones:

_X_ 1. Names –VIA INFORMED CONSENT FORM ONLY
_X__ 2. Street address, city, county, 5-digit zip code –VIA INFORMED CONSENT FORM ONLY
___ 3. Months and dates (years are OK) and ages >89 (unless all persons over 89 years are aggregated into a single category)
___ 4. Telephone numbers
___ 5. Fax numbers
___ 6. E-mail addresses
_X__ 7. Social security number –VIA INFORMED CONSENT FORM ONLY
___ 8. Medical record number
___ 9. Health plan beneficiary number
___ 10. Account number
___ 11. Certificate/license number
___ 12. Vehicle identification number (VIN) and/or license plate number
___ 13. Device identifiers and serial numbers
___ 14. URLs (Uniform Resource Locators)
___ 15. Internet protocol address number

___ 16. Biometric identifiers, such as finger and voice prints
___ 17. Full face photographic images or any comparable images
___ 18. Any other unique identifying number, characteristic, or code such as patient initials

ii. Can you limit your collection of personal health identifiers to just dates, city/state/zip, and/or "other unique identifier" (#18 above)?
___ Yes – then your dataset may qualify as a Limited Data Set – please complete a Data Use Agreement and attach to your protocol. Then go to question #4.
__X_ No – Go to question #3.

iii. Is obtaining patient Authorization "impracticable"?
___ Yes – Authorization may qualify to be waived by the IRB. Provide a detailed justification why you believe obtaining an Authorization is impracticable. (If the Waiver is approved and your sample size is less than 50, disclosures of data outside the Military Healthcare System must be tracked by the PI.)
_X__ No – Research subjects will need to sign a HIPAA Authorization. Complete the Authorization and attach to this protocol.

iv. What precautions will you take to protect the confidentiality of research source documents (Case Report Forms, questionnaires, etc.), the research datafile, and the master code (if any)?

The subject's name, social security number and address will be collected on the informed consent form but will not be used on the data collection sheet or the S-TOFHLA and REALM forms. All data will be collected by the associate investigator. The sociodemographic data sheets (Attachment E) and study results will be collected by the associate investigator at the time of testing and secured in a locked area in Building 1, Room A251, WRAMC, in accordance with the rules of WRAMC DCI and the DoD/Uniformed Services University of Health Sciences (USUHS). Data results will be entered into a SPSS spreadsheet on a desktop computer by the researcher and will be maintained by the study investigators. Data will be kept confidential and only viewed by the research team, WRAMC Department of Clinical Investigation officials, USUHS Graduate School of Nursing dissertation committee members

v. When will you destroy the research source documents, datafile, and the master code?
The research team in the Nursing Research Service will keep the research data for up to three years after the end of the study. Then all the information will be destroyed.

vi. Will research data with any personal health identifiers be sent outside of WRAMC?
___ Yes   X No

k. Data collection:

Data Collection Approach

The investigative team will collect data in a private area/room located in the internal/family medicine clinic at WRAMC. After informed consent is obtained, the following sociodemographic data will be collected: health professional training status: gender, age, marital status, race/ethnicity, and pay grade/rank. Although the investigators believe that the majority of participants will be patients with no formal health related education or training, we will collect data on health professional training of each study participant in order to describe the degree to which the study sample has been formally educated in a health care role. Volunteers will then be asked to take the S-TOFHLA and REALM.

Data will be collected from a convenience sample of military members. Each study participant will be asked to participate in one session lasting approximately 20 minutes. Data results will be entered into a SPSS spreadsheet by the researcher.

<u>Overview of Measurement Instruments used in Data Collection</u>

The two most widely accepted instruments for measuring health literacy are the Test of Functional health Literary in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM). The shortened version of the S-TOFHLA and the REALM will be used in this study.

The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages for a total of 36 Cloze items (comprehension skills measured). The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The S-TOFHLA has been shown to have good internal consistency (reliability) (cronbrach's alpha = .68 [4 numeracy items] and .97 [36 Cloze items] for reading comprehension) and concurrent validity compared to the long version of the TOFHLA (r=.91) and the REALM (r=.80). It takes 8-12 minutes to administer (<u>See</u> Attachment A for copy of S-TOFHLA)..

Unlike the S-TOFHLA which measures comprehension (ability to read and understand numbers), the REALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects are asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes by personnel with minimal training and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Attachment B for copy of REALM). The criterion validity for the REALM has been established through correlation with other standardized reading tests at p <0.0001: Pearson Oral Reading Test-Revised (.97); Slosson Oral Reading Test-Revised (.96); and Wide Range Achievement Test (WRAT) reading subtest (WRAT-R) (.88). The REALM has good reliability (test-retest .99) and inter-rater (.99) and as indicated above, is highly correlated with the S-TOFHLA (r=.80). While the S-TOFHLA and REALM have not been used in an active-duty military sample, the instruments have been successfully used in a variety of civilian populations to measure health literacy. Nevertheless, the lack of previous testing in the military and results of the third specific aim will be factors to consider when interpreting the results of this preliminary study.

1. Sample size estimation:

The statistical power and sample-size estimation were powered on the associations (gender) proposed for this preliminary study and were established with collaboration with the DoD/USUHS biostatistician. After discussion, a sample size of 200 was decided upon to ensure that the sample size is large enough to conduct the analysis proposed for this study and account for attrition. As this is a preliminary study, the power analysis was determined a need for a sample size of 150. With 150 subjects, a two group t-test with a .05 two-sided significance level will have .80 power to detect a difference of 11.5 points on the S-TOFHLA when the sample sizes in the two groups are 30 and 120 respectively, assuming the standard deviation of S-TOFHLA scores is 20. It is estimated that 20% of the sample will be female. This sample size will yield a margin of error of 7.3 percentage points for estimating the prevalence of "inadequate" health literacy skills, assuming a .95, 2-sided confidence interval and a prevalence of .30.

m. Data analysis: .
We will describe data analysis specific to each of the study aims:

Specific Aim 1: Data will be collected at the nominal, ordinal, and scale level. Univariate statistics (frequency distributions, measures of central tendency, categorical groupings of literacy level, e.g., estimated reading level, marginal health literacy) will be used to describe SCDs, health professional status, and health literacy skills among in active duty military personnel. The S-STOFHLA scores and standard cutoffs will be used to estimate the proportion of the sample with adequate and inadequate functional health literacy skills. Average scores will be compared across demographic subgroups using a two group (male and female) (independent) t-test and/or ANOVA.

Specific Aim 2: Data will be collected as indicated above and at the nominal, ordinal and scale level. Pearson's product moment correlation will be used to explore the strength of the relationship between two continuous variables such as the S-TOFHLA and REALM, and S-TOFHLA and age in years. Multiple linear regression will be used to describe joint relationships where the dependent variable is the S-TOFHLA score as continuous variable and the independent variables are the SDCs. Categorical independent variables will be dummy coded for inclusion in the multiple linear regression model if relationships suggest performing predictive analysis. Independent samples Chi square will also be used to examine relationships between health literacy skills and categorical variables -- gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) and predictive analysis will be conducted using logistic regression as appropriate.

Specific Aim 3: The instruments used to measure health literacy are the same as the previous two specific aims. Cronbach's Alpha will be used to assess reliability (internal consistency) of the S-TOFHLA on the numeracy and Cloze items and a correlation between the two sections determined. Then, the correlation between the REALM and the total scores for the S-TOFHLA, the total score for the numeracy items and the total score for the Cloze items will be assessed with the Pearson's product moment correlation. Spearman rank correlation coefficient will also be used to compare the three S-TOFHLA categories and the four categories of the REALM.

11. REFERENCES:

Arnold, C. L., Davis, T. C., Berkel, H. J., Jackson, R. H., Nandy, I., & London, S. (2001). Smoking status, reading level, and knowledge of tobacco effects among low-income pregnant women. *Prev Med, 32*(4), 313-320.

Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. R. (1999). Development of a brief test to measure functional health literacy. *Patient Educ Couns, 38*(1), 33-42.

Beers, B. B., McDonald, V. J., Quistberg, D. A., Ravenell, K. L., Asch, D. A., & Shea, J. A. (2003). Disparities in Health literacy between African American and non-African American Primary Care Patients. *Abstract. Journal of General Internal Medicine, 18 (Supplement 1)*, 169.

Bennett, C. L., Ferreira, M. R., Davis, T. C., Kaplan, J., Weinberger, M., Kuzel, T., et al. (1998). Relation between literacy, race, and stage of presentation among low-income patients with prostate cancer. *J Clin Oncol, 16*(9), 3101-3104.

Burns, N., & Grove, S. K. (2005). *The practice of nursing research: conduct, critique, and utilization* (5th ed.). St. Louis, MO: Elsevier

Dewalt, D. A., Berkman, N. D., Sheridan, S., Lohr, K. N., & Pignone, M. P. (2004). Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med, 19*(12), 1228-1239.

Dictionary.Com. (2006). Literacy. from http://dictionary.reference.com/search?q=literacy

DoDHA (2006). Department of Defense 2005 Survey of Health Related Behaviors Among Active Duty Miltiary Personel. Prepared by RTI International, December 2006.

HHS. (2000). *Healthy People 2010: Understanding and Improving Health.* Retrieved. from
http://www.healthypeople.gov/Document/tableofcontents.htm#Volume2.

IOM. (2004). *Health Literacy: A Prescription to End Confusion.* IOM (Institute of Medicine).
Washington, D.C.: The National Academies Press.

Kalichman, S. C., Benotsch, E., Suarez, T., Catz, S., Miller, J., & Rompa, D. (2000). Health literacy and
health-related knowledge among persons living with HIV/AIDS. *Am J Prev Med, 18*(4), 325-331.

Kirsch, I. S., Jungeblut, A., Jenkins, L., & Kolstad, A. (2002). *Adult Literacy in America: A First Look at
the Results of the National Adult Literacy Survey (3rd ed).* Washington, D.C.: U.S. Department of
Education: National Center for Education Statistics.

Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. . (2006). *The Health Literacy of America's Adults:
Results from the 2003 National Assessment of Adult Literacy.*

Lindau, S. T., Tomori, C., Lyons, T., Langseth, L., Bennett, C. L., & Garcia, P. (2002). The association of
health literacy with cervical cancer prevention knowledge and health behaviors in a multiethnic
cohort of women. *Am J Obstet Gynecol, 186*(5), 938-943.

Parker, R. M., D. W. Baker, et al. (1995). "The test of functional health literacy in adults: a new
instrument for measuring patients' literacy skills." J Gen Intern Med 10(10): 537-41.

Parker. (2000). Health literacy: a challenge for American patients and their health care providers. *Health
Promot. Int., 15*(4), 277-283.

Rudd, R., Kirsch, I., & Yamamoto, K. (2004). *Literacy and Health in America: Policy Information
Report.* Princeton, NJ: Educational Testing Service.

Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., et al. (2002). Association of
Health Literacy with Diabetes Outcome. *JAMA, 288*(4), 475-482.

Selden, C. R., Zorn, M., Ratzan, S., & Parker, R. M. (2000). *National Library of Medicine Current
Bibliographies in Medicine: Health Literacy (NLM Pub. No. CBM 2000-1).* Bethesda, MD: U.S.
Department of Health and Human Services/National Institutes of Health.

Simonds, S. K. (1974). Health Education as Social Policy. *Health Education Monogram*
2, 1-25.

Tones, K. (2002). Health literacy: new wine in old bottles? *Health Educ. Res., 17*(3), 287-290.

Williams, M. V., R. M. Parker, et al. (1995). "Inadequate functional health literacy among patients
at two public hospitals." JAMA, 274(21): 1677-82.

Williams, M.V., Baker, D.W.,. Honig, E.G., Lee T.M., & Nowlan, A. (1998), Inadequate literacy is a
barrier to asthma knowledge and self-care. Chest, 114(4).

Zorn, M., Allen, M. P., & Horowitz, A. M. (2004). *National Library of Medicine Current Bibliographies
in Medicine: Understanding Health Literacy and its Barriers (NLM Pub. No. CBM 2004-1).*
Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health

12. FACILITIES/ORGANIZATIONS TO BE USED:

WRAMC will be the organization/facility used to conduct this study. A private area in the internal/family
medicine clinic will used to conduct this study.

13. ROLE AND RESPONSIBILITIES OF EACH INVESTIGATOR AND COLLABORATOR:

The principal investigator will exercise overall control of the study. Under guidance from the principal
investigator, the associate investigator will consent subjects and conduct the study.

14. TIME REQUIRED TO COMPLETE:
Anticipated start date – October 2007
Expected completion date – October 2008
We anticipate that it will take 1 year to complete this study. Table 2 depicts time line.

15. BUDGET:

Will any outside organization provide funding or other resources? Yes ( ) No (XX)

As part of his doctoral training at DoD/USUHS, CAPT Weld personally obtained the copyright licenses to use the S-TOFHLA and REALM in this research study.

16.   ENVIRONMENTAL IMPACT STATEMENT:

Does any part of this protocol generate any of the following regulated waste?

a. Hazardous chemical waste	Yes ( )	No (XX)
b. Regulated Medical Waste .	Yes ( )	No (XX)
c. Radioactive Waste	Yes ( )	No (XX)

If yes to any, please indicate at what stage and how much? Not applicable.

17. INVESTIGATOR COMPLIANCE with AR 40-38, Clinical Investigation Program; DCI SOP, the NARMC DoD Multiple Project Assurance (MPA) and the WRAMC Federal-Wide Assurance (FWA):

a. I have read and will comply with AR 40-38, Clinical Investigation Program, and the DCI SOP.

b. I have read and will comply with the "Potential Conflicts of Interest in Clinical Research at WRAMC" in the DCI SOP document dated December 2004 on the DCI web site.

c. I have read and will comply with the NARMC DoD Multiple Project Assurance (MPA) and the WRAMC Federal-Wide Assurance granted by the Office for Human Research Protection, Department of Health and Human Services.

d. I certify that any outside funds and/or other resources (other than requested from DCI) being provided for this study are listed above in this application under Budget.

18. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR IN HUMAN SUBJECTS RESEARCH:
The principal investigator is the individual who is primarily responsible for the actual execution of the clinical investigation. He is responsible for the conduct of the study, obtaining subjects' consent, providing necessary reports, and maintaining study documents. The principal investigator:
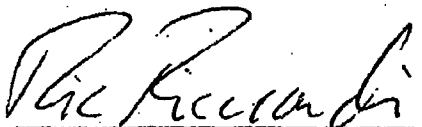
a. I will not enroll a subject into a study until the study has been approved by the appropriate authority and, when appropriate, the subject's primary care physician has granted approval for him/her to enter a study.

b. By signing this protocol, I warrant that any use of Protected Health Information for reviews preparatory to research met the following requirements:

       i.   The review of Protected Health Information was done solely to prepare a research protocol, or for similar purposes preparatory to research;

       ii.   No Protected Health Information was taken outside the Military Health System; and

       iii.   This review of PHI was necessary for research purposes

c. I am responsible for assuring that the prospective volunteer is not participating as a subject in other research that will significantly increase the research risks.

d. I am responsible for assuring the quality of each subject's consent in accordance with current federal regulations. This will include ensuring that any "designee" that obtains consent on my behalf is completely conversant with the protocol and is qualified to perform this responsibility.

e. I will obtain the appropriate WRAMC clearance for advertisements used to recruit research subjects.

f. I will not accept any outside personal remuneration for implementation of a study.

g. I will take all necessary precautions to ensure that the study does not generate hazardous chemical waste.

h. I will obtain the proper WRAMC clearance for all presentations, abstracts, and publications. The following require WRAMC approval:
    i. Reports involving WRAMC patients.
    ii. Reports that cite WRAMC in the title or byline.
    iii. Reports of WRAMC approved clinical investigation or research.
    iv. Reports of research performed at WRAMC.
    v. Reports of research conducted by WRAMC assigned personnel.

i. I must submit to the Department of Clinical Investigation:

    i. Any source of outside funding.
    ii. An Annual Progress Report (APR) due in the anniversary month of the protocol's initial approval.
    iii. Reports of adverse effects occurring in subjects as a result of study participation.
    iv. An Addendum, prior to any changes made to the study or a change in the funding status.
    v. A Final Report within 30 days following termination of a study.
    vi. A listing of presentations, abstracts, and publications arising from the study for inclusion in the DCI Annual Research Progress Report.

j. I will maintain a Study File that must be kept for three years following completion of the study if no IND/IDE used (32 CFR 219.115(b). If IND medication or IDE appliances are used, the file must be kept for 2 years after FDA approval and can then be destroyed; or if no application is filed or approved, until 2 years after the study is discontinued and FDA notified (21CFR 312.62(c). The records should be kept in the Department/Service where the research took place (AR 40-38). If I am scheduled to PCS or ETS, these records will be given to a new Walter Reed PI or the Department/Service Chief.

This file may be inspected at any time by DCI, the Clinical Investigation Regulatory Office (CIRO), the Food and Drug Administration (FDA), and/or other regulatory agencies responsible for the oversight of research. This file will include:

i. The approved protocol and applicable addenda.

ii. The approval memorandum and WRAMC Clinical Investigation and Human Use Committee minutes (as appropriate) granting approval to initiate the study.

iii. Other applicable committee minutes [e.g., Radioactive Drug Research Committee (RDRC); the Surgeon General's Human Subjects Research Review Board].

iv. Each Volunteer Agreement Affidavit (DA 5303-R) signed by the subject and a Witness, if one is required by the Walter Reed Human Use Committee (HUC).

v. Annual Progress/Final Reports.

vi. Reports of adverse effects occurring in subjects as a result of study participation.

vii. Reports of any significant new findings found during the course of the study.

viii. All study documents generated from study date.

ix. Publications, abstracts, reprints resulting from study data.

x. All information pertaining to an investigational drug or device.

xi. For HIV research studies, approval of the Chief, Infectious Disease Service.

k. I will be familiar with all applicable regulations governing research, and will adhere to all of the requirements outlined in the NARMC DoD Multiple Project Assurance (MPA) and the WRAMC Federal-Wide Assurance granted by the Office for Human Research Protections, Department of Health and Human Services.

understand that if I fail to comply with any of these responsibilities, all projects for which I am an investigator may be suspended. I also acknowledge the above Application for Clinical Investigation Project; Request for Approval of Clinical Investigation Study Proposal; Environmental Impact Statement; Investigator Compliance Statement; and Responsibilities of the Principal Investigator in Human Subject Research.

PRINCIPAL INVESTIGATOR
COL Richard Ricciardi, AN
Chief, Nursing Research Service
Department of Nursing
Phone: 202-782-7025
Fax: 202-782-5058
Walther Reed Army Medical Center

20. ASSOCIATE INVESTIGATORS' SIGNATURE:

CAPT Konstantine Keian Weld, Public Health Service
Doctoral Student Uniformed Service University of the Health Sciences (USU)
Phone: 240-638-6075/240-453-6080 or 6084
Fax: 240-453-6109

21. OTHER SIGNATURES for APPROVAL:

I concur with the submission of this proposal to the Clinical Investigation Committee and/or Human Use Committee for review and approval.

SUSAN ANNICELLI
COL AN
Deputy Commander for Nursing
WRAMC

ATTACH SUPPORTING DOCUMENTATION HERE

Attachments

A. Short version of Test of Functional Health Literacy in Adults (S-TOFHLA) - Note that short version of TOFHLA consists of selected portions of TOFHLA as indicated in protocol and Attachment C S-TOFHLA and REALM Information Sheet

B. Rapid Estimate of Adult Literacy in Medicine (REALM)

C. S-TOFHLA and REALM Information Sheet

D. Proposed Advertisement for Flyer and Poster (will be large version of Flyer)

E. Sociodemographic characteristics collection sheet

F. CV/Resumes - 1 paper copy and one copy on disk or attached to email of no more than 2 pages from All Principal and Associate Investigators submitting their initial protocol. Updates required thereafter as requested or per modifications to keep current in DCI library)

G. Associate Investigator's Human Subject Research Training/CITI Certificates from DoD and USUHS

H. General Impact Statement

Attachment A

PEPPERCORN BOOKS & PRESS INC

TOFHLA
TEST OF FUNCTIONAL HEALTH LITERACY IN ADULTS

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FOR USE IN TESTING OR RESEARCH

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Konstantine Weld, HHS/OCCFM, Rockville, MD

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Test of Functional Health Literacy in Adults

Standard Print Version
English, 12 point font

Test of Functional Literacy in Adults
TOFHLA
NUMERACY

HAND PATIENT PROMPT FOR EACH QUESTION. THEN READ EACH QUESTION, AND RECORD RESPONSES. STOP AT THE END OF 10 MINUTES.

PREFACE FIRST QUESTION WITH:
"These are directions you or someone else might be given at the hospital. Please read each direction to yourself. I will ask you some questions about what it means."

PREFACE SUCCEEDING QUESTIONS WITH:
"Have a look at this one" OR "Here is another direction you might be given."

PROMPT 1:
If you take your first tablet at 7:00 am, when should you take the next one?

N-1		
	(1)	(0)

And the next one after that?

N-2		
	(1)	(0)

What about the last one for the day, when should you take that one?

N-3		
	(1)	(0)

PROMPT 2
Could you take that medicine on July 10, 1993?

N-4		
	(1)	(0)

PROMPT 3:
If you began taking your medicine Tuesday, when should you take it next?

N-5		
	(1)	(0)

What day would you take it after that?

N-6		
	(1)	(0)

PROMPT 4
If this were your score, would your blood sugar be normal today?

N-7		
	(1)	(0)

PROMPT 5:
When is your next appointment?

N-8		
	(1)	(0)

Where should you go?

N-9		
	(1)	(0)

PROMPT 6:
How many of those pills should you take?

N-10		
	(1)	(0)

PROMPT 7:
How many times can you get that prescription refilled?

N-11		
	(1)	(0)

When is the date of issue?

N-12		
	(1)	(0)

When is six months from the date of issue?

N-13		
	(1)	(0)

PROMPT 8:
If you eat lunch at 12:00 noon, and you want to take this medicine before lunch, what time should you take it?

N-14		
	(1)	(0)

If you forgot to take it before lunch, what time should you take it?

N-15		
	(1)	(0)

PROMPT 9:
Let's just say the last time you came to the clinic was on Jul 12, 1992. When would you have to reapply for financial aid?

N-16		
	(1)	(0)

PROMPT 10:
Let's say that after deductions, your monthly income and other resources are $1,129. And, let's say you have 3 children. Would you have to pay for your care at that clinic?

N-17		
	(1)	(0)

Total Raw Score

COMMENTS

Test of Functional Literacy in Adults
TOFHLA
READING COMPREHENSION

HAND PATIENT THE READING COMPREHENSION PASSAGES TO BE COMPLETED. FOLD BACK THE PAGE OPPOSITE THE TEXT SO THAT THE PATIENT SEES ONLY THE TEXT.

PREFACE THE READING COMPREHENSION EXERCISE WITH:

"Here are some other medical instructions that you or anybody might see around the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and 4 possible words that could go in the blank appear just below it. I want you to figure out which of those 4 words should go in the blank, which word makes the sentence make sense. When you think you know which one it is, circle the letter in front of that word, and go on to the next one. When you finish the page, turn the page and keep going until you finish all the pages."

STOP AT THE END OF 12 MINUTES

PASSAGE A: X-RAY PREPARATION

PASSAGE B: MEDICAID RIGHTS AND RESPONSIBILITIES

PASSAGE C: HOSPITAL CONSENT FORM

PASSAGE A

A1	(1)	(0)
a.		
b.		
c.		
d.		

A2	(1)	(0)	A3	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A4	(1)	(0)	A5	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A6	(1)	(0)	A7	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

Sub-Total

PASSAGE A

Your doctor has sent you to have a _____ X-ray.

    a. stomach
    b. diabetes
    c. stitches
    d. germs

You must have an _____ stomach when you come for _____.

    a. asthma   a. is.
    b. empty   b. am.
    c. incest   c. if.
    d. anemia   d. it.

The X-ray will _____ from 1 to 3 _____ to do.

    a. take   a. beds
    b. view   b. brains
    c. talk   c. hours
    d. look   d. diets

THE DAY BEFORE THE X-RAY.

For supper have only a _____ snack of fruit, _____ and jelly,

    a. little   a. toes
    b. broth   b. throat
    c. attack   c. toast
    d. nausea   d. thigh

with coffee or tea.

A8	(1)	(0)	A9	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A10	(1)	(0)	A11	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A12	(1)	(0)
a.		
b.		
c.		
d.		

A13	(1)	(0)	A14	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A15	(1)	(0)	A16	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

Sub-Total

After _____ , you must not _____ or drink
    a. minute,   a. easy
    b. midnight,   b. ate
    c. during,   c. drank
    d. before,   d. eat

anything at _____ until _after_ you have _____ the X-ray.
    a. ill   a. are
    b. all   b. has
    c. each   c. had
    d. any   d. was

THE DAY OF THE X-RAY.

Do not eat_____.
    a. appointment.
    b. walk-in.
    c. breakfast.
    d. clinic.

Do not _____ , even _____.
    a. drive,   a. heart.
    b. drink,   b. breath.
    c. dress,   c. water.
    d. dose,   d. cancer.

If you have any _____ , call the X-ray _____ at 616-4500.
    a. answers,   a. Department
    b. exercises,   b. Sprain
    c. tracts,   c. Pharmacy
    d. questions,   d. Toothache

B17	(1)	(0)
a.		
b.		
c.		
d.		

B18	(1)	(0)	B19	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

B20	(1)	(0)
a.		
b.		
c.		
d.		

B21	(1)	(0)	B22	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

B23	(1)	(0)
a.		
b.		
c.		
d.		

B24	(1)	(0)	B25	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

Sub-Total

PASSAGE B

I agree to give correct information to _____ if I can receive Medicaid.
        a. hair
        b. salt
        c. see
        d. ache

I _____ to provide the county information to _____ any
  a. agree   a. hide
  b. probe   b. risk
  c. send   c. discharge
  d. gain   d. prove

statements given in this _____ and hereby give permission to
      a. emphysema
      b. application
      c. gallbladder
      d. relationship

the _____ to get such proof. I _____ that for
    a. inflammation   a. investigate
    b. religion   b. entertain
    c. iron   c. understand
    d. county   d. establish

Medicaid I must report any _____ in my circumstances
      a. changes
      b. hormones
      c. antacids
      d. charges

within _____ (10) days of becoming _____ of the change.
    a. three   a. award
    b. one   b. aware
    c. five   c. away
    d. ten   d. await

B26	(1)	(0)
a.		
b.		
c.		
d.		

B27	(1)	(0)
a.		
b.		
c.		
d.		

B28	(1)	(0)
a.		
b.		
c.		
d.		

B29	(1)	(0)
a.		
b.		
c.		
d.		

B30	(1)	(0)
a.		
b.		
c.		
d.		

B31	(1)	(0)
a.		
b.		
c.		
d.		

B32	(1)	(0)
a.		
b.		
c.		
d.		

B33	(1)	(0)
a.		
b.		
c.		
d.		

B34	(1)	(0)
a.		
b.		
c.		
d.		

B35	(1)	(0)
a.		
b.		
c.		
d.		

B36	(1)	(0)
a.		
b.		
c.		
d.		

Sub-Total

I understand _____ if I DO NOT like the _____ made on my

    a. thus
    b. this
    c. that
    d. than

    a. marital
    b. occupation
    c. adult
    d. decision

case, I have the _____ to a fair hearing. I can _____ a

    a. bright
    b. left
    c. wrong
    d. right

    a. request
    b. refuse
    c. fail
    d. mend

hearing by writing or _____ the county where I applied.

    a. counting
    b. reading
    c. calling
    d. smelling

If you _____ TANF for any family _____ , you will have to

    a. wash
    b. want
    c. cover
    d. tape

    a. member,
    b. history,
    c. weight,
    d. seatbelt,

_____ a different application form. _____ , we will use

a. relax
b. break
c. inhale
d. sign

a. Since,
b. Whether,
c. However,
d. Because,

the _____ on this form to determine your _____ .

    a. lung
    b. date
    c. meal
    d. pelvic

    a. hypoglycemia.
    b. eligibility.
    c. osteoporosis.
    d. schizophrenia.

TOFHLA: Reading Comprehension
Scoring Key

12 Point Font

Passage A	Passage A	Passage B	Passage B	Passage C	Passage C
A1 a	A8 b	B17 c	B26 c	C37 b	C45 c
A2 b	A9 d	B18 a	B27 d	C38 d	C46 a
A3 d	A10 b	B19 d	B28 d	C39 a	C47 b
A4 a	A11 c	B20 b	B29 a	C40 c	C48 c
A5 c	A12 c	B21 d	B30 c	C41 b	C49 d
A6 a	A13 b	B22 c	B31 b	C42 b	C50 d
A7 c	A14 c	B23 a	B32 a	C43 d	
	A15 d	B24 d	B33 d	C44 a	
	A16 a	B25 b	B34 c		
			B35 b		
			B36 b		

TOFHLA Numeracy
12 point font - English

Prescription Bottle Labels and Prompts
(to be laminated)

The prescription bottle labels for items 1, 2, 3, 6, 7, & 8 should be duplicated, cut to size, laminated, and taped on an actual prescription bottle that can to handed to the patient to read.

The prompts for items 4, 5, 9, & 10 should be duplicated on card stock (heavy paper), cut to size, and laminated to be handed to the patient to read.

1.   GARFIELD IM   16 Apr 93
        FF941858 Dr. LUBIN, MICHAEL

        PENICILLIN VK
        250MG 40/0
        Take one tablet by mouth four
        times a day

        02   (4 of 40)

2.   GARFIELD IM   16 Apr 92
        FF941861 Dr. LUBIN, MICHAEL

        AMOXICILLIN LIQ
        125MG/5ML 150ML1/0

        Refrigerate-Shake well; discard
        after March 15, 1993

        02 12   (1 of 1)

3.   GARFIELD IM   16 Apr 93
                     FF941860 Dr. LUBIN, MICHAEL

METHOTREXATE
2.5 MG   10/0

Take every third day.

08 11 14 31   (1 out of 10)

6.   GARFIELD IM   16 Apr 93
                     FF941860 Dr. LUBIN, MICHAEL

TETRACYCLINE
250 MG   40/0

Important: Finish all this
medication unless otherwise
directed by prescriber

02 03 04 11 31   (4 of 40)

7.   GARFIELD IM   28 Dec 92
        FF941857 Dr. LUBIN, MICHAEL

        PHENOBARBITAL
        30 MG   90/2

        After two refills or six months
        from date of issue, this
        prescription can only be refilled
        by authority of physician.
        (2 refills)

        01 08   (9 of 90)

8.   GARFIELD IM   16 Apr 93
        FF941862 Dr. LUBIN, MICHAEL

        DOXYCYCLINE

        100 MG   20/0

        Take medication on empty
        stomach one hour before or
        two to three hours after a
        meal unless otherwise
        directed by your doctor.

        02 11   (0 of 20)

4. Normal blood sugar is 60 - 150.

 Your blood sugar today is 160.

5.

CLINIC APPOINTMENT

CLINIC:	Diabetic		LOCATION: 3rd floor
			a.m.
DAY:	Thurs.	DATE: April 2nd	HOUR: 10:20
			p.m.
Issued by			

YOU MUST BRING YOUR PLASTIC CARD WITH YOU

9. For clinic care, you only must apply once each six months.

10. You can get care at no cost if after deductions your monthly income and other resources are less than:

 $ 581 for a family of one $ 1,196 for a family of four
 $ 786 for a family of two $ 1,401 for a family of five
 $ 991 for a family of three $ 1,606 for a family of six.

Attachment B (Name and date of birth will not be collected)

RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE (REALM) Examiner's Instruction Sheet

Terry Davis, PhD, Michael Cronch, MN, Sandy Long, PhD

The Rapid Estimate of Adult Literacy in Medicine (REALM) is a screening instrument to assess an adult patient's ability to read common medical words and lay terms for body parts and illnesses. It is designed to assess medical professionals in estimating a patient's literacy level so that the appropriate level of patient education materials or oral instructions may b3 used. The test takes two to three minutes to administer and score. The REALM has been correlated with other standardized tests (Family Medicine, 1993: 25:391-5).

Directions to the Examiner:

1. Examiner should say to the patient:
   "This survey is to help us figure out the best type of patient education materials to give you. The survey only takes 2 to 3 minutes to do"

2. Give the patient a laminated copy of the "REALM" Patient Word List.

3. Examiner should hold an unlaminated "REALM" Score Sheet on a clipboard at an angle so that the patient is not distracted by your scoring procedure.

4. Examiner should say:
   "I want to hear you read as many words as you can from this list. Begin with the first word on List 1 and read aloud. When you come to a word you cannot read, do the best you can or say "blank" and go on to the next word."

5. If the patient takes more than five seconds on a word say "blank" and point to the next word, if necessary, to move the patient along. If the patient begins to miss every word; have him/her pronounce only known words.

6. Count as an error any word not attempted or mispronounced. Score by:
   - (/) after each mispronounced word.
   - (-) after each word not attempted.
   - (+) after each word pronounced correctly.

7. Count the number of correct words for each list and record the numbers in the "SCORE box. Total the numbers and match the total score with its grade equivalent in the table below.

8. Record the "Realm" generated reading level on the Examiner's Score Sheet and in the Education/Learning History section of the Social and Patient Education History assessment form in the Medical Record.

GRADE EQUIVALENT		
Raw Score	**Grade Range**	
0-18	3rd Grade and Below	Will not be able to read most low literacy materials; will need repeated oral instructions, materials composed primarily of illustrations, or audio or video tapes.
19-44	4th to 6th Grade	Will need low literacy materials; may not be able to read prescription labels.
45-60	7th to 8th Grade	Will struggle with most patient education materials.
61-66	High School	Will be able to read most patient education materials.

Rapid Estimate of Adult Literacy in Medicine

Date _____ Examiner _____ Reading Level _____

List 1		List 2		List 3	
fat	_____	fatigue	_____	allergic	_____
flu	_____	pelvic	_____	menstrual	_____
pill	_____	jaundice	_____	testicle	_____
dose	_____	infection	_____	colitis	_____
eye	_____	exercise	_____	emergency	_____
stress	_____	behavior	_____	medication	_____
smear	_____	prescription	_____	occupation	_____
nerves	_____	notify	_____	sexually	_____
germs	_____	gallbladder	_____	alcoholism	_____
meals	_____	calories	_____	irritation	_____
disease	_____	depression	_____	constipation	_____
cancer	_____	miscarriage	_____	gonorrhea	_____
caffeine	_____	pregnancy	_____	inflammatory	_____
attack	_____	arthritis	_____	diabetes	_____
kidney	_____	nutrition	_____	hepatitis	_____
hormones	_____	menopause	_____	antibiotics	_____
herpes	_____	appendix	_____	diagnosis	_____
seizure	_____	abnormal	_____	potassium	_____
bowel	_____	syphilis	_____	anemia	_____
asthma	_____	hemorrhoids	_____	obesity	_____
rectal	_____	nausea	_____	osteoporosis	_____
# of (+) Responses in List 1: _____		# of (+) Responses in List 2: _____		# of (+) Responses in List 3: _____	

Raw Score _____

LSU Health Sciences Center

SCHOOL OF MEDICINE IN SHREVEPORT

Department of Medicine

School of Medicine in Shreveport
School of Allied Health Professions
School of Graduate Studies

October 26, 2006

Konstantine Keian Weld
Attn: CDR Keian Weld HHS/OPHS/OCCFM
1101 Wootton Parkway
Rockville, MD 20852

Dear Keian Weld,

Thank you for your recent REALM order. We are excited to learn of your interest in literacy and in the REALM. Enclosed are the materials you requested.

The REALM is a useful screening instrument and research tool for use with adults in health care settings. The tablet contains 50 examiner record forms that may be photocopied. The laminated purple page is the word list that is given to the patient. Information about test development, administration and scoring can be found in the *REALM Administration Manual*. Additional materials are available upon request.

I have included an invoice with the order; payment is due one month after date of the invoice.

The REALM has been copyrighted; however, it is in the public domain. No permission requests are needed.

The most up to date review of literacy testing in health care research is a chapter that Dr. Davis wrote with colleagues who developed the TOHFLA (Test Of Functional Health Literacy In Adults). The chapter is found in a recent AMA book, Understanding Health Literacy. Joanne G, Schwartzberg, M.D. is the editor. You may call her to order the book, 312-464-5355.

If you have any questions, do not hesitate to call (318) 675-4585 or e-mail me at mbocch@lsuhsc.edu. Thank you so much!

Best Regards,

Mary Bocchini
Research Associate,
Health Education and Literacy

Louisiana State University Health Sciences Center · School of Medicine in Shreveport · Department of Medicine
1501 Kings Highway · P.O. Box 33932 · Shreveport, Louisiana 71130-3932
phone (318) 675-5980 fax (318) 675-7176 www.lsuhsc.edu

RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE (REALM) Examiner's Instruction Sheet

Terry Davis, PhD, Michael Crouch, MN, Sandy Long, PhD

The Rapid Estimate of Adult Literacy in Medicine (REALM) is a screening instrument to assess an adult patient's ability to read common medical words and lay terms for body parts and illnesses. It is designed to assess medical professionals in estimating a patient's literacy level so that the appropriate level of patient education materials or oral instructions may b3 used. The test takes two to three minutes to administer and score. The REALM has been correlated with other standardized tests (Family Medicine, 1993: 25:391-5).

Directions to the Examiner:

1. Examiner should say to the patient:
   "This survey is to help us figure out the best type of patient education materials to give you. The survey only takes 2 to 3 minutes to do"

2. Give the patient a laminated copy of the "REALM" Patient Word List.

3. Examiner should hold an unlaminated "REALM" Score Sheet on a clipboard at an angle so that the patient is not distracted by your scoring procedure.

4. Examiner should say:
   "I want to hear you read as many words as you can from this list. Begin with the first word on List 1 and read aloud. When you come to a word you cannot read, do the best you can or say "blank" and go on to the next word."

5. If the patient takes more than five seconds on a word say "blank" and point to the next word, if necessary, to move the patient along. If the patient begins to miss every word; have him/her pronounce only known words.

6. Count as an error any word not attempted or mispronounced. Score by:
   - (/) after each mispronounced word.
   - (-) after each word not attempted.
   - (+) after each word pronounced correctly.

7. Count the number of correct words for each list and record the numbers in the "SCORE box. Total the numbers and match the total score with its grade equivalent in the table below.

8. Record the "Realm" generated reading level on the Examiner's Score Sheet and in the Education/Learning History section of the Social and Patient Education History assessment form in the Medical Record.

GRADE EQUIVALENT

Raw Score	Grade Range	
0-18	3rd Grade and Below	Will not be able to read most low literacy materials; will need repeated oral instructions, materials composed primarily of illustrations, or audio or video tapes.
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45-60	7th to 8th Grade	Will struggle with most patient education materials.
61-66	High School	Will be able to read most patient education materials.

Rapid Estimate of Adult Literacy in Medicine
REALM©
Terry Davis, PhD, Michael Crouch, MD, Sandy Long, PhD

Date _____ Examiner _____ Reading Level _____

List 1		List 2		List 3	
fat	_____	fatigue	_____	allergic	_____
flu	_____	pelvic	_____	menstrual	_____
pill	_____	jaundice	_____	testicle	_____
dose	_____	infection	_____	colitis	_____
eye	_____	exercise	_____	emergency	_____
stress	_____	behavior	_____	medication	_____
smear	_____	prescription	_____	occupation	_____
nerves	_____	notify	_____	sexually	_____
germs	_____	gallbladder	_____	alcoholism	_____
meals	_____	calories	_____	irritation	_____
disease	_____	depression	_____	constipation	_____
cancer	_____	miscarriage	_____	gonorrhea	_____
caffeine	_____	pregnancy	_____	inflammatory	_____
attack	_____	arthritis	_____	diabetes	_____
kidney	_____	nutrition	_____	hepatitis	_____
hormones	_____	menopause	_____	antibiotics	_____
herpes	_____	appendix	_____	diagnosis	_____
seizure	_____	abnormal	_____	potassium	_____
bowel	_____	syphilis	_____	anemia	_____
asthma	_____	hemorrhoids	_____	obesity	_____
rectal	_____	nausea	_____	osteoporosis	_____
# of (+) Responses in List 1: _____		# of (+) Responses in List 2: _____		# of (+) Responses in List 3: _____	

Raw Score _____

List 1	List 2	List 3
fat	fatigue	allergic
flu	pelvic	menstrual
pill	jaundice	testicle
dose	infection	colitis
eye	exercise	emergency
stress	behavior	medication
smear	prescription	occupation
nerves	notify	sexually
germs	gallbladder	alcoholism
meals	calories	irritation
disease	depression	constipation
cancer	miscarriage	gonorrhea
caffeine	pregnancy	inflammatory
attack	arthritis	diabetes
kidney	nutrition	hepatitis
hormones	menopause	antibiotics
herpes	appendix	diagnosis
seizure	abnormal	potassium
bowel	syphilis	anemia
asthma	hemorrhoids	obesity
rectal	nausea	osteoporosis
incest	directed	impetigo

Attachment C

Information Sheet:
The Short Version –Test of Functional Health Literacy in Adults (S-TOFHLA) & the Rapid Estimate of Adult Literacy in Medicine (REALM)

S-TOFHLA

The S-TOFHLA is a modified version of the TOFHLA which consists of the following:

A. Administration of reading comprehension passages A and B of the full TOFHLA (See Attached S-TOFHLA at Attachment A).

B. Four numeracy items (#1, 4, 5 and 8) that are samples from prescription bottle labels and prompts you might see in health care setting (See Attachment A). For the convenience of the reader, the journal article published on the development of the S-TOFHLA is attached and contains a listing of the four numeracy items along with sample reading comprehension passages as set forth below.

Numeracy items and sample reading comprehension passage

NUMERACY ITEM 1 *(Label on prescription bottle)*

Take one tablet by mount every 6 hours as needed.

ORAL QUESTION: If you take your first tablet at 7:00 a.m., when should you take the next one?
CORRECT ANSWER: "1:00 p.m."

NUMERACY ITEM 2 *(Prompt card)*

Normal blood sugar is 60–150. Your blood sugar today is 160.

ORAL QUESTION: If this was your score, would your blood sugar be normal today?
CORRECT ANSWER: "No"

NUMERACY ITEM 3 *(Prompt card)*

CLINIC APPOINTMENT		
CLINIC: Diabetic		LOCATION: 3rd floor
DAY: Thurs.	DATE: April 2nd	HOUR: 10:20 a.m. / p.m.
Issued by:		
YOU MUST BRING YOUR PLASTIC CARD WITH YOU		

ORAL QUESTION: When is your next appointment?
CORRECT ANSWER: "April 2nd" or "Thursday, April 2nd"

NUMERACY ITEM 4 *(Label on prescription bottle)*

Take medication on empty stomach one hour before or two to three hours after a meal unless otherwise directed by your doctor.

ORAL QUESTION: If you eat lunch at 12:00 noon, and you want to take this medicine before lunch, what time should you take it?
CORRECT ANSWER: "11:00" or "before 11:00"

--Sample S-TOFHLA Reading Passages – Next Page--

Reading Comprehension Passage A (page 1)

Your doctor has sent you to have a _____ X-ray.
a. stomach
b. diabetes
c. stitches
d. germs

You must have an _____ stomach when you come for ____.
a. asthma   a. is
b. empty   b. am
c. incest   c. if
d. anemia   d. it

The X-ray will _____ from 1 to 3 _____ to do.
a. take   a. beds
b. view   b. brains
c. talk   c. hours
d. look   d. diets

THE DAY BEFORE THE X-RAY

For supper have only a _____ snack of fruit, _____ and jelly, with coffee or tea.
a. little   a. toes
b. broth   b. throat
c. attack   c. toast
d. nausea   d. thigh

REALM

Unlike the S-TOFHLA which focuses on comprehension skills, the REALM measures de-coding skills. The REALM is administered by having subjects pronounce sixty-six (66) words commonly used in medical/health care settings and determining how many of the words were pronounced correctly. The REALM score is then used to provide an estimated reading grade level. A copy of the REALM word list is attached below.

Attachment D

The recruiting poster and flyer follows on the next page. The flyer on the following page will be enlarged and posted in the waiting room of the family/general practice clinic on ward 73 at WRAMC. The poster will be removed when the investigator team leaves the clinic.

A RESEARCH STUDY ON HEALTH LITERACY IN ACTIVE DUTY PERSONNEL at a Major Medical Center
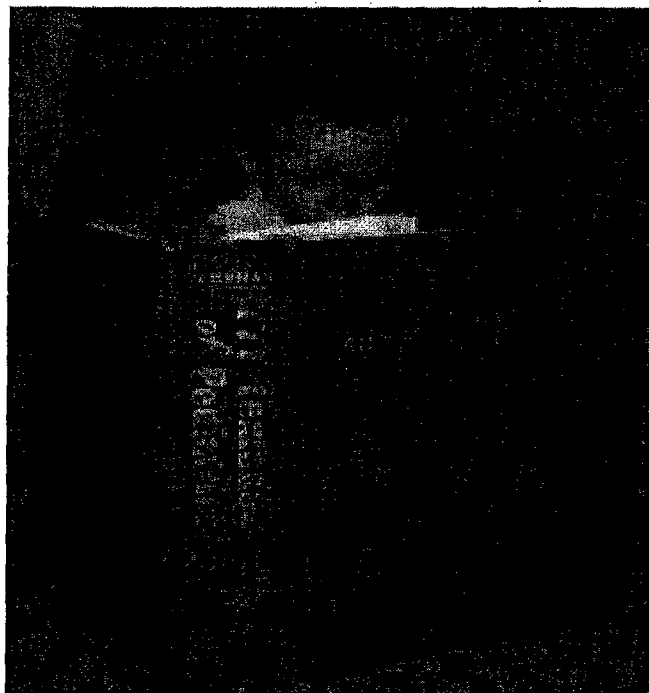
Active-Duty Military members (staff, patients or visitors) are invited to participate in a research study being conducted in the Family/Internal Medicine clinic on Ward 73. The purpose of the study is to assess the health literacy of active-duty personnel. This study is open to all active-duty personnel who do not have a visual or speech impairment that would prevent them from completing the health literacy surveys. You will not personally benefit from participating in this study but the results of this study will be used to assist health care professionals to better understand the concept of health literacy and to develop patient education and teaching materials.

It will take approximately 15 minutes to complete this study. Active-duty personnel who are interested in participating should come to the Family/Internal Medicine clinic on Ward 73 or call COL Richard .icciardi at (202) 782-7025.

Attachment E

Sociodemographic Collection Sheet

1. Gender: Male _____ Female _____

2. Age in years on last birthday: _____

3. Marital Status: 3A.   Single, never married   _____

                        3B.   Married   _____

                        3C.   Separated   _____

                        3D.   Widowed   _____

4. Current pay grade (E1-O10);   _____

5. Highest level of education now:

               5A.   Did not graduate from high school   _____

               5B.   GED certificate   _____

               5C.   High School Diploma   _____

               5D.   Some College
                      but not 4-year college degree   _____

               5E.   4-year college degree or higher   _____

6. Race/Ethnicity:

               6A.   White/Non-Hispanic   _____

               6B.   African American/Non-Hispanic   _____

               6C.   Hispanic   _____

               6D.   American Indian Alaska Native   _____

               6E.   Asian   _____

               6F.   Other   _____

7. Has received health professional training, e.g., medic: (yes or no) _____

8. Do you work at WRAMC in a health care position (yes or no)   _____

Attachment F

CAPT KONSTANTINE KEIAN WELD, USPHS
17211 Palomino Court
Olney, MD 20832
(301) 570-8686

EDUCATION

Ph.D. in Nursing – (Candidate) - Program focus on Federal/military health care
DoD/Uniformed Services University of the Health Sciences, Bethesda, MD
- Participation through extramural training
- Comprehensive examination completed – dissertation/project phase

LL.M. (Law & Government Program – Health law & policy track)
American University, Washington College of Law, Washington, D.C.
- Graduate law certification in Health Law/Regulatory Policy
- 2002 LL.M. Legal Research and Writing Award

J.D. (Health law emphasis)
St. Louis University, St. Louis, MO

B.S. in Nursing
University of North Carolina, Greensboro, NC

PROFESSIONAL LICENSES/ASSOCIATIONS

- State bar associations - West Virginia, Missouri, & District of Columbia (D.C.)
- Licensed to practice law before the U.S. Courts of Appeals for the 4th Cir. and D.C. Cir.
- Licensed professional registered nurse in North Carolina and West Virginia

POSITIONS

PHS Representative
- Currently detailed by the Assistant Secretary for Health (ASH)/Surgeon General (SG) to represent the PHS Commissioned Corps (Corps) in Board of Inquiry cases involving allegations of ethical misconduct at NIH

Director for Workforce Policy & Plans Div. (OS/OPHS/Force Management (OCCFM), 2003-Present (permanent supervisory assignment)
- Advisor to the ASH, Deputy ASH (Operations), SG and OCCFM Director on Corps force management issues, Top Secret Security Clearance
- Responsible for drafting and publishing Federal regulations and Corps policy issuances
- Responsible for working with HHS/OGC and other HHS/non-HHS organizations on legal/legislative and policy issues related to the Corps and the Nation's public health
- Represents HHS/Corps on Armed Forces Tax Council (JAG/legal officer workgroup), DoD Health Affairs Special Pay Committee & DoD Military Advisory Panel

Commissioned Corps Policy Advisor, PSC/Division of Commissioned Personnel, 2001 - 2003
- Personnel advisor to Director, Division of Commissioned Personnel and Surgeon General
- Responsible for drafting and publishing Federal regulations and Corps policy issuances

Senior Program Management Consultant – HRSA – Office of Special Programs, 2000-2001
- Responsible for drafting Federal regulations & legislative proposals for healthcare mortgage refinancing program and managing a financial portfolio of hospital mortgages

Senior Assistant Attorney General for the State of West Virginia, 1996 - 2000
- Served as the Director of Litigation/Chief Counsel for a $290 million State Health and Disability Insurance Fund
- Represented client agencies and state-insured companies in various Federal and state courts including the W.Va. Supreme Court of Appeals, Department of Labor Federal administrative law hearings, U.S. Bankruptcy Court, U.S. District Court, & the U.S. Courts of Appeals for the Fourth Circuit and District of Columbia Circuit
- Supervised 1-2 attorneys & 2-5 paralegals/secretaries
- Assigned to other civil and criminal matters, e.g., civil rights violations, employee grievances

Assistant Attorney General for the State of West Virginia, 1992-1996
- Represented state agencies in Federal and state court on variety of matters as directed by Attorney General – civil & criminal, with primary focus of practice on health/disability & insurance law

U.S. Military, 1981 - 2000
- Nurse Corps officer in U.S. Air Force (USAF) & U.S. Army Reserves/NG, 1989 - 2000
- Enlisted Army soldier plus ROTC & Airborne School, 1981-1984

Clinical Registered Nurse, 1986-1989
- Medical/Surgical Nurse at St. Louis Univ. Medical Ctr. (cardiology/critical care), 1987-1989
- Completed critical care course at St. Louis Community College
- Psychiatric Nurse at Charter Hills Hospital, 1986-1987

PUBLISHED LEGAL OPINIONS - ATTORNEY OF RECORD

- Underwood v. Elkay Mining, Inc., 105 F.3rd 946 (4th Cir. 1997)
- Beckley v. W.Va. Division of Public Safety, 193 W.Va. 258, 455 S.E.2d 817
- Mitchem v. Bailey Energy, Inc., 21 Black Lung Rep. 1-161, 1999 DOLBRB LEXIS 34
- Lester v. Mack Coal Co., 21 Black Lung Rep. 1-126, 1999 DOLBRB LEXIS 12

ASSOCIATIONS

- American Association of Health Lawyers
- American Association of Nurse Attorneys
- Public Health Law Association

ADDITIONAL ACTIVITIES AND TRAINING

- Has completed 5 Response Missions/Deployments including Hurricane Katrina
- Completed DoD Humanitarian Response Course
- Volunteer Attorney for clients infected with HIV/AIDs – Completed workshop on legal issues for HIV/AIDs, clients, e.g., ADA law , employment law, medical care issues
- Continuing legal education- Recent Ex. Trial Skills Series, Brd. of VA legal workshop
- IRB Human Subjects Researcher Course/Certificate & CITI Annual Researcher Certification
- Army JAG School - Non-resident courses - Basic & Advanced contract law, Federal employment law, Federal Claims, Federal Civilian Personnel Law/Labor-Mgmt
- HHS Basic Project Officer Training & HHS Secretary's Emergency Response Team Course
- Interagency Institute for Federal Health Care Executives Course
- Army Medical Department Healthcare Credentials Data Base Course
- Army Medical Department Basic, Advanced, & S2/S3 Operations Courses
- USAF Nurse Mgmt Course & Organ Procurement Training
- M.S. in Nursing at Marshall University, WV – 15 Credits – Theory & Research focus
- HFMA Accounting/Finance certification course & Basic Healthcare Finance Course
- 10+ Healthcare finance & accounting courses during HRSA assignment

Attachment G

Certificate of Training Completion

This certifies that

Konstantine Weld

has successfully completed the following approved training,
as required by the Human Research Protection Program:
CITI Biomedical Science Course on 04/26/2007.
The individual named above is now authorized to engage in the
HRPP activities which he or she is qualified and approved to
perform.

Ellen P. Embrey
Component Designated Official

05/11/2007
Date

This certification expires on
04/26/2008

Attachment H

Resource Impact Statement Sign-Off Sheet

PRINCIPAL INVESTIGATOR: Col Richard Ricciardi   DATE: 24 OCT 2007

TITLE OF PROTOCOL: "ASSESSMENT OF HEALTH LITERACY RATES IN A
SAMPLE OF ACTIVE-DUTY MILITARY PERSONNEL AT A MAJOR MEDICAL CENTER

PROTOCOL FUNDING SOURCE: No funding. Principal Investigator working with doctoral
nursing student at DoD/USUHS Graduate School of Nursing – Dissertation Research Project

Title of Impact Statement	Indicate "Yes" or "Not Applicable" to Your Protocol (from Instructions page)	Signature Block* Name, Rank, Title, Service, Department, Date
DCI Laboratory	Not Applicable	*
DPALS	Not Applicable	Attach completed and signed Impact Statement to this Sign-Off Sheet.
Pharmacy	Not Applicable	Attach completed and signed Impact Statement to this Sign-Off Sheet.
Telemedicine	Not Applicable	Attach completed and signed Impact Statement to this Sign-Off Sheet.
Information Management (DOIM)	Not Applicable	Attach completed and signed Impact Statement to this Sign-Off Sheet.
Nursing	Yes	Attach completed and signed Impact Statement to this Sign-Off Sheet.
Radiology	Not Applicable	*
Nuclear Medicine	Not Applicable	*
PAD	Not Applicable	*
Amputee Program	Not Applicable	*
Other	Support from Chief, Medicine Clinic	*[signature] Russell O. Davis MAJ, MC, USA

* Department Chief or Designee: Sign in the above signature block. Signature indicates the
support and willingness of the Department to provide the services requested for this research
project. If necessary, list the resources needed from your department to support this research
project in the space below. Attach additional sheets if necessary:

VOLUNTEER AGREEMENT AFFIDAVIT
For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you. If future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) – VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____ , SSN _____

having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal

representative for _____ to participate in _____

Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel at a Major Medical Center

under the direction of ___ **COL Richard Ricciardi, AN, Nursing Research Service, (202) 782-7025 or DSN 662-7025**

conducted at ___ **WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001**

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

COL Richard Ricciardi, AN, Nursing Research Service, Dept. of Nursing, (202) 782-7025 or DSN 662-7025, or his designee

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

CENTER JUDGE ADVOCATE OFFICE – (202) 782-1550 OR DSN 662-1550

at   **WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001**

(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I /the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I/the person I represent is otherwise entitled.

LIMITATIONS TO MEDICAL CARE ARE DESCRIBED IN PART B

PART A (2) – ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD)

I, _____ , SSN _____ , having full capacity

to assent and having attained my _____ birthday, do hereby volunteer for _____

_____ participate in _____

under the direction of _____

Conducted at   **WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001**

(Name of Institution
(Continue on Reverse)

NOT APPLICABLE

DA FORM 5303-R, MAY 89   PREVIOUS EDITIONS ARE OBSOLETE

PART A(2) – ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd)

The implications of my voluntary participation; the nature, duration, and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

---

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

CENTER JUDGE ADVOCATE OFFICE – (202) 782-1550 OR DSN 662-1550

at _____ **WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001** _____
(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

LIMITATIONS TO MEDICAL CARE ARE DESCRIBED IN PART B

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: (Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25

DESCRIPTION OF THIS STUDY

You are being asked to be in this research study because you are an active-duty military service member. Your participation is entirely voluntary. Refusal to participate will not result in any penalty or loss of benefits to which you are otherwise entitled, nor will your refusal affect your employment or career status.

The purpose of the study is to assess the health literacy rates in group of active-duty military members such as yourself. Health literacy is defined as the ability of people get and use basic health information and service so they make good health decisions for themselves. Studies in non-military personnel have shown that some people have low health literacy which may make it difficult for them to make good health care decisions. People with low health literacy may also need their doctor or nurse to spend more time helping them with their health decisions.

If you agree to be in this study, you will be asked to provide information about yourself such as your gender, age, marital status and your military rank. Then, you will be asked to take two tests that will measure your health literacy. You should be able to complete both tests in about 15-20 minutes. The first test takes about 8-12 minutes and you will be asked to answer questions that may come up in a health setting such as your doctor's office or when you look at medicine bottle. The second test takes about 2-3 minutes and you will be asked to verbally repeat medical words to a member of the study team. The data we collect in this study will not be linked to your name in any way.

(Left margin, rotated text): Approved by the WRAMC HUC/IRB on 18 September ; This form expires on 18 September 2007 (per CIC) for WU # 07-75039. Initials [signature]

I do ☐ do not ☐   (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

NOT APPLICABLE

REVERSE OF DA FORM 5303-R, MAY 89

PART B – TO BE COMPLETED BY INVESTIGATOR (Cont'd)

AMOUNT OF TIME FOR YOU TO COMPLETE THIS STUDY

You will be part of this study for a total of about 15-20 minutes. After answering the short questions and taking the two tests, your participation in the study is complete.

APPROXIMTE NUMBER OF PEOPLE TAKING PART IN THIS STUDY

There will be up to 200 active-duty military personnel taking part in this study.

POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY

There are no expected risks or discomforts from being in this study.

POSSIBLE BENEFITS OF BEING IN STUDY

You will not benefit from being in this study, but the information we learn may help us understand health literacy better. The information from this study may assist the Department of Defense (DoD) Military Health System to develop patient education materials and medical questionnaires that are better understood by patients.

CONFIDENTIALITY (PRIVACY) OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep records of your being in this study. These records may be looked at by people from the Walter Reed Department of Clinical Investigation, the Walter Reed Human Use Committee, the Army Clinical Investigation Regulatory Office (CIRO), and other government agencies, such as the DoD/Uniformed Services University of the Health Sciences (USUHS), as part of their duties. These duties include making sure that research subjects are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws. Your name will not appear in any published paper or presentation related to this study.

Data results will be entered into a spreadsheet on a desktop computer by the researcher and will be maintained by the study investigators. Data results will also be viewed by USUHS Graduate School of Nursing dissertation committee members. The research records will be kept secured in a locked area in Building 1, Room A251, for up to three years after the end of the study. Then all the information will be destroyed.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA Authorization form for this study will be provided to you separately, and you will be asked to sign that form.

CONDITIONS UNDER WHICH YOUR TAKING PART IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you become ineligible for medical care at military hospitals.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)	
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS		
	SIGNATURE OF WITNESS		DATE

NOT APPLICABLE

REVERSE OF DA FORM 5303-R, MAY 89

PART B -- TO BE COMPLETED BY INVESTIGATOR (Cont'd)

ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY
You will not receive any payment for being in this study.

COMPENSATION TO YOU IF INJURED AND LIMITS TO YOUR MEDICAL CARE
Should you be injured as a direct result of being in this study, you will be provided medical care for that injury at no cost to you. You will not receive any compensation (payment) for injury. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal or associate investigator before you enroll in this study

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care.

WHAT WILL HAPPEN IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND INSTRUCTIONS FOR STOPPING EARLY
You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the principal investigator as soon as possible. By leaving this study at any time, you in no way risk losing your right to medical care

COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY
There is no charge to you for taking part in this study.

Please feel free to ask any questions that will allow you to clearly understand this study.

A copy of this consent form will be provided to you.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

(left margin, rotated) Approved by the WRAMC HUC/IRB or This form expires on 18 September September 2007 (per CIC)   for WU # 07-75039. Initials

Authorization for Research Use of Protected Health Information

Protocol Title: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel at a Major Medical Center

Principal Investigator: COL Richard Ricciardi, AN   **Work Unit #: 07-75039**

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used.

1. What information will be collected?
   For this research study, we will be collecting information about your health literacy, your gender, age, marital status, race/ethnicity and your current pay grade/rank. Your name, social security number and address will be on the consent form, but will not be used on the data collection sheet or on the two tests being used in this study to measure your health literacy.

2. Who may use my PHI within the Military Healthcare System?
   The members of the WRAMC research team will have access to your PHI as stated above. Additionally, your PHI may be made available to health oversight groups such as the WRAMC Department of Clinical Investigation and Human Use Committee.

3. What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive my PHI?
   No members outside of the Military Healthcare System will receive my PHI.

4. What is the purpose for using or disclosing my Protected Health Information (PHI)?
   You will be asked to sign the consent form but no additional PHI will be collected. None of the data collection sheets used in this study will be linked to your PHI.

5. How long will the researchers keep my Protected Health Information?
   The research team in the Nursing Research Service will keep the research data for up to three years after the end of the study. Then all the information will be destroyed.

6. Can I review my own research information?
   You may look at your personal research information (consent form and HIPAA form) at any time. The data we collect in this study will not be linked to your name in any way.

7. Can I cancel this Authorization?
   Yes. If you cancel this Authorization, you will no longer be included in the research study. If you want to cancel your Authorization, please contact COL Richard Ricciardi, Nursing Research Service, Dept of Nursing, at 202-782-7025.

8. What will happen if I decide not to sign this Authorization?
   If you decide not to sign this Authorization, you will not be able to participate in this research study. Refusal to sign this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

A PHOTOCOPY OF THIS FORM MUST BE SIGNED BY ALL VOLUNTEERS.
Approved by the WRAMC Privacy Officer on *29 Oct* for WU# 07-75039   Expires   18 September 2012

9. Can my Protected Health Information be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Army Clinical Investigation Regulatory Office, the Food and Drug Administration, the DHHS Office for Human Research Protections, and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

10. Who should I contact if I have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with the WRAMC Privacy Officer, 6900 Georgia Ave., NW, Washington, DC 20307.
Telephone: 202-782-3114.

The signature below acknowledges receipt of this Authorization:

Signature: _____   Date: _____

If you are a parent, court-appointed representative, or acting as power of attorney, indicate your authority to act for the participant: _____

Print Name: _____

A copy of this signed Authorization will be provided to you.   7/21/03

January 7, 2008

MEMORANDUM FOR CAPT KONSTANTINE WELD, BSN, JD, LLM, GRADUATE SCHOOL OF NURSING

SUBJECT: Acceptance of Walter Reed Army Medical Center Institutional Review Board Approval of Protocol 07-75039, USU IRB Reference T061IR-01, for Human Research Participation (DoD Assurance No. P60001 and FWA # 0001628).

In accordance with the USUHS-WRAMC IRB Authorization Agreement, dated March 31st, 2005, the Uniformed Services University (USU) Institutional Review Board accepts the September 18, 2007 Walter Reed Army Medical Center approval of the no more than minimal risk research protocol entitled *"Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel."* This approval will be reported to the full USU IRB scheduled to meet on February 14, 2008.

The purpose of this study is to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of the national population to those of active duty military. Measurement of health literacy will be assessed from two exams: 1) the Rapid Estimate of Adult Literacy in Medicine (REALM) and 2) the short version of Test of Functional health literacy in Adults (S-TOFHLA).

This action concurs with WRAMC's approval on 18 September 2007.

To maintain USU authorization to participate in this protocol, you are required to submit copies of all approval documentation from external IRBs to the USU IRB office within 30 days of your receipt of these materials. Documents that must be forwarded to the USU IRB include all approval letters, a copy of stamped, final informed consent documents (if applicable), amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research. Continuing (annual) review documentation must be accompanied by a current USU Form 3204B.

If you have questions regarding specific issues on your protocol, or questions of a more general nature concerning human participation in research, please contact me at 301-295-0819/9534 or mpickerel@usuhs.mil.

Margaret Pickerel
Institutional Review Board Coordinator

cc: REA
       Chair, GSN

       File

Learning to Care for Those in Harm's Way

STUDENT and RESIDENT PHYSICIAN
RESEARCH PROPOSAL

VPR Stamp

Project Number:
(VPR will assign) _____

Project Title: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel

1.	**Name (Last, First, MI):**	Weld, Konstantine Keian
2.	**Percent Effort:**	100 % (Effort on awarded projects and other activities may not exceed 100%)
3.	**USU Department:**	Graduate School of Nursing, PhD Program

			Fax:	
4.	**Telephone:**	Office: 240-453-6084	301-295-9006	E-mail: kweld@usuhs.mil
5.	**USU Building/ Room No.**	GSN, Administration Office/Building A	Lab Room Number(s): Not Applicable	
6.	**Off-Site Address:**	Nursing Research Office (c/o Director, COL Richard Riccardi), Walter Reed Army Medical Center, Washington, D.C.		

7. **Type of Student/Resident:**	Student Type (select one) Year of the project (select one)

Student Type (select one)
- ☒ Graduate Student (Ph.D) or (Dr.P.H) — ☒ 1 or ☐ 2
- ☐ Graduate Student (Masters) — ☐ 1 or ☐ 2
- ☐ Medical Student — ☐ 1 or ☐ 2
- ☐ Nursing Master — ☐ 1 or ☐ 2
- ☐ Physician Assigned for Graduate Medical — ☐ 1 or ☐ 2

USU Billet Number

The following signatures attest to the validity of the above information:

Student/Resident Investigator (Signature and Date)	Research Advisor (Signature and Date)
Department Chair/Program Director (Type or Print)	Department Chair/Program Director (Signature and Date)

If Graduate Student   **If Nursing Student**

(Associate Dean for Graduate Education) (Signature and Date)	(Dean, Graduate School of Nursing) (Signature and Date)
(Associate Dean for Graduate Education) (Type or Print)	(Dean, Graduate School of Nursing) (Type or Print)

If Medical Student (both signatures are required)

(Dean, School of Medicine) (Signature and Date)	(Dean, School of Medicine) (Signature and Date)
(Dean, School of Medicine) (Type or Print)	(Associate Dean for Student Affairs) (Type or Print)

f Physician Assigned for Graduate Medical Education

(Associate Dean for Graduate Medical Education) (Type or Print)	(Associate Dean for Graduate Medical Education) (Signature and Date)

With all the above signatures, the project is approved.

8.	Name (Last, First, MI): (same as signature in Section B)	Bibb, Sandra C.		
9.	USU Department:	Graduate School of Nursing		
10.	Telephone:	Office: 301-787-4955	Fax: 3012951707	E-mail: sbibb@usuh.mil
11.	USUHS Building/ Room No.	GSN/Dean's Office, Bldg A	Lab Room Number(s): N/A	

12.	Attach a copy of your research proposal. <u>See</u> Appendices for protocol and full approved WRAMC protocol documents	☒ Yes ☐ No

13. Is this research project related to an active research project of the advisor identified in Section B? If yes, complete this Part 13; if no, proceed to Part 14. ☐ Yes ☒ No

Project Number: _____

Project Title: _____

Project Start Date: _____

Project End Date: _____

14. Anticipated Period of Performance: **Project Start Date:** October 2007   **Project End Date:** October 2008

15. **List all performance sites and indicate percentage of the work being performed at each site:**

Performance Site (Should not exceed 100%)	% of Work
USU (on-campus space and/or rented off-campus space)	
Other off-site location(s): Walter Reed Army Medical Center	100

16.	If this is year two of the project, is a USU Form 3210, Progress Report, attached?	☐ Yes ☒ No
17.	Does this project involve any classified information? (Contact the USU Security Office for guidance)	☐ Yes ☒ No
18.	Does this project involve research with foreign work? (Contact the Clinical Affairs Office for guidance)	☐ Yes ☒ No

19. What is the funding source?

☒ No Funding

☐ Graduate Education Office   ☐ USU Department/Program (Specify) _____

☐ Graduate School of Nursing   ☐ Federal (specify): _____

☐ USU Intramural   ☐ Other External Agency (Specify) _____

20.	If "Federal" or "Other External Agency" is marked, does the Sponsor allow indirect cost?	☐ Yes ☐ No
21.	If yes what is the allowable rate?	%

22. **List budget breakdown below:** (May not include non-mission essential travel, secretarial/administrative support, or scientific conferences)

	Item Description	Dollar Amount
a.	Office Supplies: pencils, paper, pens, highlighters, clips, folders, notebooks	$400
b.	Locked cabinet drawers	$190
c.	Computer toner cartridges (5 @ $90.00 per item)	$450
d.	Poducing/Printing recruiting poster/pamphlets	$350
e.		$
		$
	Grand total (if more space is needed, attach an additional sheet on plain paper; include here with grand total)	$1390.00

23.	If this is an annual assurance supplement (year two of the project), mark the "Change" box in each assurance section if work will deviate from work previously approved. Attach the appropriate assurance form(s), approval notification or forward the appropriate form directly to the proper committee as directed. If no change has occurred, mark the "No Change" box.

24.	Does this project involve human research? (including human cells, tissues or fluids, surveys or database use or development) (Submit the USU Form 3204: Research Involving Human Subjects (new or modification/addendum) with the application to Office of Research, Room A1032).	☒ Yes ☐ No ☐ Change ☐ No Change ☐ N/A

25.	Is this project **specifically** covered in all relevant details by the preexisting IRB approval of your advisor's protocol identified in Section C.
	     a. If yes, attach a completed USU Form 3204, Research Involving Human Subjects , a copy of the USU approval letter and, if applicable, a copy of the approved informed consent.
	     b. If no, attach a completed USU Form 3204, Research Involving Human Subjects.
	     c. If Change, contact the IRB Office for guidance.
		☒ Yes ☐ No ☐ Change
		 ☐ No Change ☐ N/A

26.	Does this project involve the study of existing data?
	 If yes, list the data source(s) below:
	
	         Location: _____
	         Location: _____
		☐ Yes ☒ No ☐ Change
		 ☐ No Change ☐ N/A

27.	Does this project involve human research at a non-USUHS location(s),? If yes, list the location(s) below and attach a copy of the approval letter from each off-site location:
	
	         Location: Walter Reed Army Medical Center – Internal/family clinic on Ward 73 _____
	         Location:
		☒ Yes ☐ No
		 ☐ Change ☐ No Change

,.	Does this project involve animal research at USU?	☐ Yes ☒ No ☐ Change ☐ No Change

29.	Is this project **specifically** covered by the preexisting IACUC approval of the advisor's protocol identified in Section C?
	     a. If yes, complete Number 30 of this section.
	     b. If no, forward a completed USU Form 3206, Animal Study Proposal to DLAM.
	     c. If Change, contact DLAM for guidance.
		☐ Yes ☐ No ☐ Change
		 ☐ No Change ☒ N/A

30.	Have you submitted USU Form 3206C, Conveyance with Standard Animal Use Procedures, to DLAM to obtain a conveyance approval? List the advisor's Animal Protocol Number (APN) and Title below:
	
	     Animal Protocol Number: _____
	     Animal Protocol Title: _____
		☐ Yes ☐ No ☐ Change
		 ☐ No Change ☒ N/A

31.	If you have submitted your USU Form 3206, Animal Study Proposal, to DLAM and have been issued an APN or if this is the second year of the project, list your APN and Animal Protocol Title below:
	     Animal Protocol Number: _____
	     Animal Protocol Title: _____	

32.	Does this project involve animal research at a Non-USU location, including AFFRI? If yes, list the location(s) below and attach a copy of the approval letter from each off-site location:
	
	     Location: _____
	     Location:
		☐ Yes ☒ No ☐ Change
		 ☐ No Change

33. Does this project involve any of the following safety hazards? (Mark all that apply) ☐ Yes ☒ No ☐ Change ☐ No Change

    ☐ Dangerous Materials   ☐ Controlled Substances   ☐ Extremely Hazardous Chemicals
    ☐ Class 3 or 4 Lasers   ☐ High Intensity (>85 decibels) Sound   (If you checked this box please attach a list.)
    ☐ Human Blood, Tissue, or Body
       Fluids   ☐ Other:

34. Have you discussed this requirement with the Pharmacy?	☐ Yes ☐ No ☒ N/A	
35. Is this project <u>specifically</u> covered by the preexisting Biosafety approval of your advisor's protocol identified in Section C?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
36. Is Appendix 4, Biosafety Committee Information, attached?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
37. Does this project involve biosafety research at AFFRI? If yes, attach a copy of the approval notification.	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A

38. Does this project involve the use of recombinant preparations?	☐ Yes ☒ No ☐ Change ☐ No Change	
39. Is this project <u>specifically</u> covered by the preexisting rDNA/DNA approval of your advisor's protocol identified in Section C?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
40. Is Appendix 4, Biosafety Committee Information, attached?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
41. Does this project involve rDNA or DNA research at AFFRI? If yes, attach a copy of the approval notification.	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A

Does this project involve the use of CDC select agents?	☐ Yes ☒ No ☐ Change ☐ No Change	
Is this project <u>specifically</u> covered by the preexisting CDC approval of your advisor's protocol identified in Section C?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
44. Is Appendix 4, Biosafety Committee Information, attached?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
45. Does this project involve CDC research at AFFRI? If yes, attach a copy of the approval notification.	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A

46. Does this project involve the use of radioactive materials?	☐ Yes ☒ No ☐ Change ☐ No Change	
47. Is this project <u>specifically</u> covered by the preexisting radioactive materials approval of your advisor's protocol identified in Section C?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
48. Is Appendix 5, Radiation Safety Committee Information, attached?	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A
49. Does this project involve radioactive materials research at AFFRI? If yes, attach a copy of the approval notification.	☐ Yes ☐ No ☐ Change	☐ No Change ☒ N/A

50. Does your research involve the use of human cadaver material?	☐ Yes ☒ No ☐ Change ☐ No Change	

Upon completion of this project, a **Final Progress Report** must be submitted to the Office of Research.

)mit the USU Form 3210 with appropriate signatures (unless other arrangements have been made with the Office of Research). Attach a copy of your abstract. The University assurance offices may require additional closeout documents (contact the administrative office of each committee to determine). All USU forms can be downloaded from the Office of Research website at www.usuhs.mil/research/index2.html.

APPENDICES

Appendix A. Protocol per USU Form 3202 instructions – Short Version of full WRAMC approved protocol

Appendix B. WRAMC Approved Protocol and Accompanying Documentation

Approval letter to begin research and attachments:

A. Short version of Test of Functional Health Literacy in Adults (S-TOFHLA) - Note that short version of TOFHLA consists of selected portions of TOFHLA as indicated in protocol and Attachment C S-TOFHLA and REALM Information Sheet

B. Rapid Estimate of Adult Literacy in Medicine (REALM)

C. S-TOFHLA and REALM Information Sheet

D. Proposed Advertisement for Flyer and Poster (will be large version of Flyer)

E. Sociodemographic characteristics (SDCs) collection sheet

F. CV/Resumes - 1 paper copy and one copy on disk or attached to email of no more than 2 pages from All Principal and Associate Investigators submitting their initial protocol. Updates required thereafter as requested or per modifications to keep current in DCI library)

G. Associate Investigator's Human Subject Research Training/CITI Certificates from DoD and USUHS

H. General Impact Statement

APPENDIX A
(USU Form 3202 Research Protocol Version)

Specific Aim(s) -- The **two primary and one secondary specific aims** of this study are:

1. To identify the literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional Health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).
2. To examine the relationship between limited health literacy skills and gender, race/ethnicity, pay grade/rank, age, education level, and marital status in a sample of active-duty military personnel.
3. A secondary aim of this study is to evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

Background and Significance

At least one-third of the population lacks the health literacy skills to effectively use their respective health system. Results from the recent 2003 National Assessment of Adult Literacy (NAAL) indicate that on a 4-level scale ranging from below-basic to proficient health literacy, only 25 million adults in the United States have proficient health literacy while 75-million adults have health literacy skills at the basic or below basic level (Kutner, 2006). Literacy is the ability to read and write or knowledge of a particular subject (Dictionary.Com, 2006). Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (Selden, Zorn, Ratzan, & Parker, 2000)." Achieving proficient health literacy depends upon individual ability, the suitability of the health information from a health literacy perspective, and/or both.

Limited health literacy has been linked to higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited health literacy have also been also been linked to individuals who are non-Caucasian, have a lower education level, and/or income, and may differ by gender (Institute of Medicine (IOM) 2004; Kutner, 2006).

In the active-duty military population, the extent of limited health literacy is unknown and no surveys and/or research was found in Cumulative Index to Nursing & Allied Health Literature (CINAHL) and Pubmed databases involving military personnel. The IOM has however, identified military recruits as a population known to have limited literacy skills and thus, suspected of having limited health literacy skills. Because of this and the concern that other military members may lack proficient health literacy skills, the IOM has also recommended that DoD develop and support programs that will effectively reduce the negative impact of limited health literacy and consider exploring ways to make health materials more appropriate and user friendly (IOM, 2004).

The concept of "health literacy" was first identified in a 1974 paper titled Health Education as Social Policy (Selden et al., 2000; Simonds, 1974). In the 1974 paper, Simonds discussed the link between health literacy and health education and called for minimum standards for "health literacy" for all school grade levels. Since that time, the concept of health literacy has been defined in numerous ways with varying emphasis on the skill sets required for health literacy and personal empowerment. The most common definition of health literacy used by the scientific and clinical practice communities is the one developed for a study by the National Library of Medicine (NLM) literacy to aid in debate over how to define health literacy and advance health literacy programs (Selden et al., 2000). For the NLM study, health literacy was viewed from a skills-based perspective and health literacy was defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make

appropriate health decisions" (Selden et al., 2000). This conceptual definition has been adopted by the IOM and Healthy People 2010 (HHS, 2000) and the majority of the 3500 citations in the NLM bibliography, "Health Literacy," (Selden et al., 2000) and 651 citations in the NLM bibliography "Understanding Health Literacy and its Barriers," (Zorn, Allen, & Horowitz, 2004), rely upon this definition (Tones, 2002).

When the 1992 National Adult Literacy Survey (NALS) was conducted, the nationwide survey found that about 90 million U.S. adults (out of 191 million or 47%) could not accurately and consistently locate, match, and integrate information from newspapers, advertisements, or forms (Kirsch, Jungeblut, Jenkins, & Kolstad, 2002). While these adults could perform a variety of straightforward tasks using printed material, they were unlikely to be able to perform, with accuracy and consistency, more challenging tasks using long or dense texts. This means that in 1992, almost half of the nationwide adult population had basic deficiencies in reading and computational skills or literacy skills that were inadequate for the many tasks needed to function successfully in the economy – including the health care economy (Parker, 2000). Moreover, of these adults, 40 million were found to be functionally illiterate with the remaining adults having only marginal literacy skills (Parker, 2000). In 2004, Rudd, Kirsch and Yamamoto created a five level health activities literacy scale (HALS) (like the 1992 literacy scale) and re-analyzed the 1992 NALS results with a focus on health related tasks. An estimated 23 million adults were found to perform health-related tasks at the lowest of five levels and 46 percent of adults performed in the bottom two levels (IOM, 2004; Rudd, Kirsch, & Yamamoto, 2004).

Results from the 2003 National Assessment of Adult Literacy (NAAL) which contained the first national assessment of health literacy are consistent with the 1992 NALS results and the Rudd, Kirsch, and Yamamoto (2004) re-analysis. The 2003 NAAL results indicate that on a scale ranging from below basic to proficient health literacy, a majority of the adults in the United States had only intermediate health literacy and 75-million adults had health literacy skills at the basic or below basic level. When these 75+ million adults encounter the health care system, they are likely to have difficulty with routine reading requirements, such as reading prescription bottles, food labels, appointment slips, self-care instructions, and health education brochures (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

Health literacy is now recognized as an important aspect of health promotion and disease prevention and critical to improving the health of our Nation and its citizens. In the military, limited health literacy may be contributing to disparities in health care utilization and improved health status even though active-duty military personnel have universal access to health care, services and information. Consider, in the context of the culture of the military health system (MHS), gender, race, educational level and income should not impact the availability of health services. The degree to which active duty military personnel are able to obtain health information and services needed to make appropriate health decisions, and improve health status is equal. All active-duty personnel have universal access to health care, and yet, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Although the percentage of military personnel classified as obese (Body Mass Index greater than 30.0) is low compared to the U.S. civilian population (12.4% vs. 31%), military personnel have shown a steady and statistically significant increase in obesity over the past 10 years (up from 8.6% in 2002 to 12.4%) (DoDHA, 2006). Hospitalizations for non battle injuries remain high relative to the Healthy People 2000 objective of 754 injuries per 100,000 ((Total DoD 2635/2679 for 2002/2005 and note that Healthy People 2010 does not specify objective rate and civilian estimates were not reported). Even with universal access to care, rates of overweight/obesity and hospitalization lag behind health improvement goals set in Healthy People 2010 (& 2000 for hospitalizations); and even, within a culture that emphasizes health promotion and disease prevention, military personnel do not currently meet health promotion objectives in such areas as blood pressure checks (81.8% vs. 95% objective) and cholesterol checks (57.2% vs. 80% objective).

To date however, there are no published research studies assessing health literacy in the active-duty military population. Little is known about the degree to which active duty personnel have the capacity to process and understand basic health information, and the subsequent impact of this capacity on health care utilization and improved health status and outcomes. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the non-military population. The **purpose of this study** is to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of non-military populations to those of active duty military.

Specific Aim 1: To identify the literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

The two most widely accepted instruments for measuring health literacy are the Test of Functional health Literary in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM). The shortened version of the S-TOFHLA and the REALM will be used in this study (See Appendix B - Approved full WRAMC protocol with S-TOFHLA and REALM at attachments A & B).

The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages for a total of 36 Cloze items (comprehension skills measured). The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The S-TOFHLA has been shown to have good internal consistency (reliability) (cronbrach's alpha = .68 [4 numeracy items] and .97 [36 Cloze items] for reading comprehension) and concurrent validity compared to the long version of the TOFHLA (r=.91) and the REALM (r=.80). It takes 8-12 minutes to administer (See Appendix B - Approved full WRAMC protocol with S-TOFHLA and REALM at attachments A & B and attachment C for short information sheet on instruments).

Unlike the S-TOFHLA which measures comprehension (ability to read and understand numbers), the REALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects are asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes by personnel with minimal training and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Appendix B - Approved full WRAMC protocol with S-TOFHLA and REALM at attachments A & B and attachment C for short information sheet on instruments). The criterion validity for the REALM has been established through correlation with other standardized reading tests at p <0.0001: Pearson Oral Reading Test-Revised (.97); Slosson Oral Reading Test-Revised (.96); and Wide Range Achievement Test (WRAT) reading subtest (WRAT-R) (.88). The REALM has good reliability (test-retest .99) and inter-rater (.99) and as indicated above, is highly correlated with the S-TOFHLA (r=.80). While the S-TOFHLA and REALM have not been used in an active-duty military sample, the instruments have been successfully used in a variety of civilian populations to measure health literacy. Nevertheless, the lack of previous testing in the military and results of the third specific aim should be factors to consider when interpreting the results of this preliminary study.

While the extent of literacy/health literacy has been assessed through the 1992 NALS, 2004 NALS/1992 re-analysis, and the 2003 NAAL (75-million adults with lowest two levels of health literacy skills), these national surveys did not use the TOFHLA or REALM. A review of the literature however, reveals that at

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least 20 research studies have used the TOFHLA, S-TOFHLA, or REALM to measure the extent of health literacy in civilian populations. These studies show that limited health literacy skills are common with significant variations in prevalence depending upon the setting and population sampled (IOM, 2004; Williams et al, 1995; Williams, et al., 1998), e.g., racial or ethnic status, general medical, HIV. These studies also suggest that segments of the U.S. population that could be considered at greatest risk for limited health literacy are those that were reported to have higher rates of limited literacy in the 1992 NALS (IOM, (2004)) and 2003 NAAL – minorities and lower income individuals.

As indicated above, health literacy skills have not been measured in the active-duty military population even though segments of the population have been identified by IOM (2004) as at risk for limited health literacy such a military recruits. Based on the sociodemographic characteristics (SDC) used in health literacy research with the national population, other segments of the active-duty military population are also at risk of limited health literacy skills, e.g., non Caucasian, and lower ranking personnel (See Appendix B - Approved full WRAMC protocol with SDC data collection sheet at attachment E). Hence, it is critically important to asses the extent of health literacy in the active-duty population.

Specific Aim 2: To examine relationship between limited health literacy skills and gender, race/ethnicity, age, pay grade/rank, education level, and marital status in a sample of active-duty military personnel.

In addition to the national literacy/health literacy surveys, studies using the TOFHLA, S-TOFHLA and REALM have reported a link between limited health literacy and gender, higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited health literacy have also been also been linked to SDCs such as being non Caucasian, lower education, and/or lower income (IOM (2004), but as indicated above, non of these linkages have been studied in an active-duty military population.

The SDCs variables of gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) were chosen for this preliminary study because they represent points of comparison between the military and national population (See Appendix B - Approved full WRAMC protocol with SDC data collection sheet at attachment E).

As for specific examples in the literature suggesting a link between limited health literacy and the aforementioned variables in the national population, there are several. For example, in a study by (Arnold et al., 2001) involving smoking status, reading level, and knowledge of tobacco effects in low-income pregnant women, there was an association between limited health literacy and race (African American). In addition, associations between limited health literacy skills and racial and ethnic status have been identified in studies involving: HIV/AIDs medication adherence (Kalichman et al., 2000); stage of prostate cancer at diagnosis (Bennett et al., 1998) and (Dewalt, Berkman, Sheridan, Lohr, & Pignone, 2004); mediating effects of literacy on race; poorer diabetic outcomes (Schillinger et al., 2002) and cervical cancer screening practices (Lindau et al., 2002). A 2003 study found evidence that there were differences in health literacy status by race (African and Non-African Americans), but noted that much more research is needed because the results may be due to problems with the instrument or more general issues surrounding the assessment of education (Beers et al., 2003). In any event, the most important observation gleaned from the information presented above is the fact that the demographic groups identified in these studies are the same demographic groups identified as being at risk in the 1992 NALS and the reanalysis by Rudd, Kirsch, and Yamamoto (2004). However, as noted in the IOM (2004) health literacy report, none of the studies identified in the field of health literacy thus far, have involved a sufficiently large random sample of adults to allow for full extrapolation to other populations. This preliminary study is an important step in understanding this phenomenon in the context of the active-duty military population.

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Additionally, if relationships are found between gender, race/ethnicity, and rank and limited health literacy skills, analysis in this study will progress to the examination of the extent to which gender, race/ethnicity, and rank concepts predict the limited health literacy skills. Health literacy research studies in the national population have demonstrated a relationship between limited health literacy and gender, race/ethnicity, knowledge, health outcomes and socioeconomic status (Bennett et al., 1998; Dewalt et al., 2004; IOM, 2004; Kalichman et al., 2000; Lindau et al., 2002).

Specific Aim 3: To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

Like the TOFHLA, the S-TOFHLA was developed and has been used in the national population. To the researcher's knowledge, the S-TOFHLA has not been used in any published military research studies. The TOFHLA was developed in 1993 and found to be a valid, reliable indicator of patient's ability to read health-related materials (Parker, et al., 1995). Construct validity for the original TOFHLA was ensured by using actual hospital medical texts for both the reading comprehension and numeracy subtexts (Nurss, et al, 1995) while concurrent validity was shown by demonstrating statistically significant correlations between the REALM and the Wide Range Achievement Test- Revised (WRAT-R). The WRAT-R is an instrument that has three subtests which measure the codes which are needed to learn the basic skills of reading, spelling, and arithmetic (IOM, 2004). Correlations of the TOFHLA with the REALM and the WRAT-R were .84 and .74, respectively ($p<0.001$) by Spearman's rank correlation. The REALM and WRAT-R also have a significant correlation of .88 (Parker, et al., 1995) (See Appendix B - Approved full WRAMC protocol with S-TOFHLA and REALM at attachments A & B).

The S-TOFHLA was developed and tested in 1997 in the same setting used for the development and testing of the TOFHLA – in a sample of 238 patient/subjects from an urban public hospital in Atlanta, Georgia. The results of the testing showed good internal consistency as reflected by a cronbach's alpha of .68 for the 4 numeracy items and .97 for the 36 Cloze items in the reading comprehension section. The correlation between the numeracy score and the reading comprehension score was .60 (Baker, et al., 1999; Williams, et al., 1995). The correlation between the S-TOFHLA and the REALM was .80 (Baker, et al., 1999; Parker, et al., 1995; Williams, et al., 1995). Correlations for subscores of the numeracy and Cloze sections were .61 and .81, respectively. All correlations were significant at $p<0.001$.

There were however, differences between the S-TOFHLA and the REALM in the mid-range of the tests in that the REALM appeared to overestimate and underestimate subject's reading ability when compared to the S-TOFHLA.. It was suspected that these differences might be due to the fact that some subjects were able to pronounce words correctly, but may still have poor reading comprehension while others may have difficulty pronouncing words in isolation (without the context of other materials on the S-TOFHLA) (Baker, et al., 1999). In any event, the development and testing of the S-TOFHLA provided a short instruments (8-12 minutes to administer) which can aid in the identification of patients who may require special efforts or new health materials to reach their health care goals. It is important therefore, to evaluate whether the instrument is a reliable, valid, and practical tool, e.g., ease and time of administration, for use in active duty military populations.

Preliminary Studies (if any) -- Not Applicable.

Experimental Design and Research Site

The overall research design for this study is descriptive prospective (Burns & Grove, 2005). The design will guide the identification and description of reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy skills and gender, rank and race/ethnicity. The design will also provide a platform for evaluating the reliability, validity and practicality of using the S-TOFHLA in a sample of active duty military personnel.

Data Collection will take place at the Internal/family medicine clinics on Ward 73 at Walter Reed Army Medical Center, Washington, D.C.

Literature Cited (numbered in order listed)

1. Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. . (2006). *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy.*
2. Dictionary.Com. (2006). Literacy. from http://dictionary.reference.com/search?q=literacy
3. Selden, C. R., Zorn, M., Ratzan, S., & Parker, R. M. (2000). *National Library of Medicine Current Bibliographies in Medicine: Health Literacy (NLM Pub. No. CBM 2000-1).* Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health.
4. IOM. (2004). *Health Literacy: A Prescription to End Confusion.* IOM (Institute of Medicine). Washington, D.C.: The National Academies Press.
5. Simonds, S. K. (1974). Health Education as Social Policy. *Health Education Monogram, 2,* 1-25.
6. HHS. (2000). *Healthy People 2010: Understanding and Improving Health.* Retrieved. from http://www.healthypeople.gov/Document/tableofcontents.htm#Volume2.
7. Zorn, M., Allen, M. P., & Horowitz, A. M. (2004). *National Library of Medicine Current Bibliographies in Medicine: Understanding Health Literacy and its Barriers (NLM Pub. No. CBM 2004-1).* Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health
8. Tones, K. (2002). Health literacy: new wine in old bottles? *Health Educ. Res., 17*(3), 287-290.
9. Kirsch, I. S., Jungeblut, A., Jenkins, L., & Kolstad, A. (2002). *Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey (3rd ed).* Washington, D.C.: U.S. Department of Education: National Center for Education Statistics.
10. Parker. (2000). Health literacy: a challenge for American patients and their health care providers. *Health Promot. Int., 15*(4), 277-283.
11. Rudd, R., Kirsch, I., & Yamamoto, K. (2004). *Literacy and Health in America: Policy Information Report.* Princeton, NJ: Educational Testing Service.
12. Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. R. (1999). Development of a brief test to measure functional health literacy. *Patient Educ Couns, 38*(1), 33-42.
13. DoDHA (2006). Department of Defense 2005 Survey of Health Related Behaviors Among Active Duty Miltiary Personel. Prepared by RTI International, December 2006.
14. Williams, M. V., R. M. Parker, et al. (1995). "Inadequate functional health literacy among patients at two public hospitals." JAMA, 274(21): 1677-82.
15. Williams, M.V., Baker, D.W., Honig, E.G., Lee T.M., & Nowlan, A. (1998), Inadequate literacy is a barrier to asthma knowledge and self-care. Chest, 114(4).
16. Kalichman, S. C., Benotsch, E., Suarez, T., Catz, S., Miller, J., & Rompa, D. (2000). Health literacy and health-related knowledge among persons living with HIV/AIDS. *Am J Prev Med, 18*(4), 325-331.
17. Bennett, C. L., Ferreira, M. R., Davis, T. C., Kaplan, J., Weinberger, M., Kuzel, T., et al. (1998). Relation between literacy, race, and stage of presentation among low-income patients with prostate cancer. *J Clin Oncol, 16*(9), 3101-3104.

18. Dewalt, D. A., Berkman, N. D., Sheridan, S., Lohr, K. N., & Pignone, M. P. (2004). Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med, 19*(12), 1228-1239.

19. Lindau, S. T., Tomori, C., Lyons, T., Langseth, L., Bennett, C. L., & Garcia, P. (2002). The association of health literacy with cervical cancer prevention knowledge and health behaviors in a multiethnic cohort of women. *Am J Obstet Gynecol, 186*(5), 938-943.

20. Beers, B. B., McDonald, V. J., Quistberg, D. A., Ravenell, K. L., Asch, D. A., & Shea, J. A. (2003). Disparities in Health literacy between African American and non-African American Primary Care Patients. *Abstract. Journal of General Internal Medicine, 18 (Supplement 1)*, 169.

21. Parker, R. M., D. W. Baker, et al. (1995). "The test of functional health literacy in adults: a new instrument for measuring patients' literacy skills." J Gen Intern Med 10(10): 537-41.

22. Arnold, C.L., Davis, T.C., Berkel, H.J., Jackson, R.H., Nandy, I., & London, S. (2001). Smoking status, reading level, and knowledge of tobacco effects among low-ijncome pregnant women. Prev. *Med.,* 32(4), 313-320.

23. Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., et al. (2002). Association of Health Literacy with Diabetes Outcome. *JAMA, 288*(4), 475-482.

24. Burns, N., & Grove, S. K. (2005). *The practice of nursing research: conduct, critique, and utilization* (5th ed.). St. Louis, MO: Elsevier

Date Stamp

PROJECT NUMBER: [   ] (Number assigned by VPR)

1. **STUDY TITLE:** (75 character maximum)
   Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel

2. **PRINCIPAL INVESTIGATOR (PI):**

Name/Rank/Title:	CAPT Konstantine Keian Weld
Degree(s):	BSN, JD, LLM
Position Title:	PHD Student/Graduate School of Nursing (GSN)
USU Department:	Graduate School of Nursing
Phones (office/lab/fax):	2406386075 N/A 3012959006
Office Location(Bldg/Rm.)	GSN, Building A, GSN Dean's Office
E-mail:	kweld@usuhs.mil

3. **EXPECTED PROJECT PERIOD:**

START DATE		END DATE
November 2007	to	November 2008

_____   _____
Principal Investigator (signature)   Date

_____   _____
Department Chair (signature)   Date

You must provide verification of scientific review (letter from scientific review committee, note addressed to the IRB from Department Chair verifying the science, etc.)

Principal Investigator: CAPT Konstantine Keian Weld

Study Title: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel

6.   SHORT ABSTRACT IN LAYPERSON'S TERMS:

In one paragraph, state broad, long-term objectives and specific aims in layperson's terms. Do not copy & paste your technical abstract. **DO NOT EXCEED 25 LINES OF TEXT (12 POINT FONT).**

Research in the national population has revealed a link between limited health literacy and disparities in health care utilization and resulting health status. Limited health literacy has also been found at higher rates among individuals who are non-Caucasian, have lower education levels and/or income, and may differ by gender. In the military health system (MHS), gender, race, educational level and income should not impact the availability of health services as all active-duty personnel have universal access to health care. Yet, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Limited health literacy may be contributing to these disparities in active duty military personnel with universal access to health care, services and information. To date, there are no published research studies assessing health literacy in the active-duty military population. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the national population. The purpose of this study is to determine health literacy rates in active duty military personnel receiving health care and services ithin a culture of universal access, and to compare the health literacy rates of the national population to those of active duty military. Using a descriptive design guided by the Health Literacy Framework, this study will conduct preliminary steps in testing the hypothesis that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, and race/ethnicity. The design will guide the identification and description of estimated reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy skills and gender, rank, Service, and race/ethnicity. This identification and description will be assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM) and short version the Test of Functional health literacy in Adults (S-TOFHLA) which are the two most widely accepted instruments for measuring health literacy. The target population for this study is active-duty military personnel while data will be collected from the accessible population which is active-duty military personnel who are permanent staff, visiting, and/or being treated at Walter Reed Army Medical Center (WRAMC).

7. BUDGET SECTION:

Personnel

Full Name (Including P.I.)		USUHS Billet No.	Role in Project	Percent Effort on Project	Salary & Fringe Compensation
a.	Not Applicable				
b.					
c.					
d.					
e.					
			Subtotal of Personnel $		

Supplies (detail required) | **Cost**

		Cost
a.	Office Supplies: pencils, paper, pens, highlighters, clips, folders, notebookd	$400
b.	Locked cabinet drawers	$190
c.	Computer toner cartridges (5 @ $90.00 per item)	$450
d.	Poducing/Printing recruiting poster/pamphlets	$350
e.		
	Subtotal of Supplies $	1390

Equipment (Unit cost must be less than $5,000)   **Cost**

		Cost
a.	Not Applicable	
b.		
	Subtotal of Equipment $	

Other Expenses (contracts, mission-essential travel, BIC and LAM charges and publication costs)   **Cost**

		Cost
a.		
b.		
c.		
d.		
e.		
	Subtotal of Other Expenses $	$0.00

	TOTAL BUDGET (this year) $	$1390.00

8. BUDGET SUMMARY:

	YEAR 01	YEAR 02	YEAR 03
Personnel			
Supplies			
Equipment			
Other			
Total			

9. PERSONNEL ROLES:

1. CAPT Konstantine Keian Weld is the principal investigator and a PhD student in the USUHS Graduate School of Nursing.

MEDICAL MONITOR'S SIGNATURE (If medical monitor is not required, state NA, and then delete the following statements and signature block.) – N/A – Study not greater than minimal risk

12. PRINCIPAL INVESTIGATOR and KEY STUDY PERSONNEL

BIOGRAPHICAL SKETCH (s): (Use 12 –Point font)

	EDUCATION – CAPT Weld Institution and Location	Degree	Year Conferred	Field of Study
a.	University of North Carolina at Greensboro	BSN	1986	Nursing
b.	St. Louis University, St. Louis, Mo.	J.D.	1989	Law
c.	American University, Washington, D.C.	LL.M.	2002	Law
d.	USUHS Graduate School of Nursing	Ph.D.	Enrolled	Nursing
e.				

RESEARCH AND PROFESSIONAL EXPERIENCE

Previous employment, experience, and honors. Include present membership(s) on any Federal Government public advisory committees. List the titles and complete references to all publications during the past three years and earlier publications pertinent to this application.

Service and Work Experience
1. Active-Duty U.S. PHS Nurse Officer   PHS Representative (Board of Inquiries   Present
(Board of Inquiries involving NIH ethics violations)
Director, Workforce Policy and Plans Division   Present
Health care program consultant (HRSA/HUD)   2000- 2001
Senior Assistant Attorney General for the State of West Virginia   1996-2000
Assistant Attorney General for the State of West Virginia   1992-2000
4. U.S. Army Nurse Corps Officer Reserve/National Guard   1993-2000
5. U.S. Air Force Nurse Corps   1989-1992

6. Cardiology Nurse (St. Louis University Medical Center)   1987-1989
7. Psych Nurse (Charter Hills Psychiatric Hospital)   1986-1987
8. Nurse Intern (Ensign U.S. PHS) St. Elizabeths' Hospital/Washington D.C.   1985

   ;enses
   . Member of Association of American Association of Nurse Attorneys
2. Member of Public Health Law Association
3. Member of W.Va., Mo. and D.C. Bars and admitted to practice law before Northern and Southern Districts of
   West Virginia and U.S. Court of Appeals for the Fourth Circuit and District of Columbia
4. R.N. License in W.Va. and N.C.

Activities/Publications
1. Factors Associated with Health Care Professionals' Choice of Written Asthma Management Plans.
   Committee member for USUHS MSN students: Chairperson Sandra C. Bibb USN (ret); Students: MAJ
   Ricky Norwood, ANC USA; MAJ John F. Meyer, ANC USA.
2. Current Participant on HHS Health Literacy workgroup

13.   RESEARCH PLAN DO NOT EXCEED 10 PAGES (use 12 point font and the section headers below)

Protocol Title: Assessment of Health Literacy Rates in a Sample of Active Duty Military Personnel

PURPOSE:

The purpose of this study is to determine health literacy rates in active duty military personnel receiving health care
~nd services within a culture of universal access, and to compare the health literacy rates of non-military
    pulations to those of active duty military.

BACKGROUND AND SIGNIFICANCE

At least one-third of the population lacks the health literacy skills to effectively use their respective health
system. Results from the recent 2003 National Assessment of Adult Literacy (NAAL) indicate that on a 4-level
scale ranging from below-basic to proficient health literacy, only 25 million adults in the United States have
proficient health literacy while 75-million adults have health literacy skills at the basic or below basic level
(Kutner, 2006). Literacy is the ability to read and write or knowledge of a particular subject (Dictionary.Com,
2006). Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand
basic health information and services needed to make appropriate health decisions (Selden, Zorn, Ratzan, &
Parker, 2000)." Achieving proficient health literacy depends upon individual ability, the suitability of the health
information from a health literacy perspective, and/or both.
        Limited health literacy has been linked to higher rates of hospitalization, lower use of preventive services,
poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of
limited health literacy have also been also been linked to individuals who are non-Caucasian, have a lower
education level, and/or income, and may differ by gender (Institute of Medicine (IOM) 2004; Kutner, 2006).
        In the active-duty military population, the extent of limited health literacy is unknown and no surveys and/or
research was found in Cumulative Index to Nursing & Allied Health Literature (CINAHL) and Pubmed databases
involving military personnel. The IOM has however, identified military recruits as a population known to have
limited literacy skills and thus, suspected of having limited health literacy skills. Because of this and the concern
that other military members may lack proficient health literacy skills, the IOM has also recommended that DoD
    velop and support programs that will effectively reduce the negative impact of limited health literacy and
  ..onsider exploring ways to make health materials more appropriate and user friendly (IOM, 2004).
        The concept of "health literacy" was first identified in a 1974 paper titled Health Education as Social Policy

(Selden et al., 2000; Simonds, 1974). In the 1974 paper, Simonds discussed the link between health literacy and health education and called for minimum standards for "health literacy" for all school grade levels. Since that time, the concept of health literacy has been defined in numerous ways with varying emphasis on the skill sets required for health literacy and personal empowerment. The most common definition of health literacy used by scientific and clinical practice communities is the one developed for a study by the National Library of ...edicine (NLM) literacy to aid in debate over how to define health literacy and advance health literacy programs (Selden et al., 2000). For the NLM study, health literacy was viewed from a skills-based perspective and health literacy was defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Selden et al., 2000). This conceptual definition has been adopted by the IOM and Healthy People 2010 (HHS, 2000) and the majority of the 3500 citations in the NLM bibliography, "Health Literacy," (Selden et al., 2000) and 651 citations in the NLM bibliography "Understanding Health Literacy and its Barriers," (Zorn, Allen, & Horowitz, 2004), rely upon this definition (Tones, 2002).

When the 1992 National Adult Literacy Survey (NALS) was conducted, the nationwide survey found that about 90 million U.S. adults (out of 191 million or 47%) could not accurately and consistently locate, match, and integrate information from newspapers, advertisements, or forms (Kirsch, Jungeblut, Jenkins, & Kolstad, 2002). While these adults could perform a variety of straightforward tasks using printed material, they were unlikely to be able to perform, with accuracy and consistency, more challenging tasks using long or dense texts. This means that in 1992, almost half of the nationwide adult population had basic deficiencies in reading and computational skills or literacy skills that were inadequate for the many tasks needed to function successfully in the economy – including the health care economy (Parker, 2000). Moreover, of these adults, 40 million were found to be functionally illiterate with the remaining adults having only marginal literacy skills (Parker, 2000). In 2004, Rudd, Kirsch and Yamamoto created a five level health activities literacy scale (HALS) (like the 1992 literacy scale) and re-analyzed the 1992 NALS results with a focus on health related tasks. An estimated 23 million adults were found to perform health-related tasks at the lowest of five levels and 46 percent of adults performed in the bottom two levels (IOM, 2004; Rudd, Kirsch, & Yamamoto, 2004).

Results from the 2003 National Assessment of Adult Literacy (NAAL) which contained the first national .sessment of health literacy are consistent with the 1992 NALS results and the Rudd, Kirsch, and Yamamoto (2004) re-analysis. The 2003 NAAL results indicate that on a scale ranging from below basic to proficient health literacy, a majority of the adults in the United States had only intermediate health literacy and 75-million adults had health literacy skills at the basic or below basic level. When these 75+ million adults encounter the health care system, they are likely to have difficulty with routine reading requirements, such as reading prescription bottles, food labels, appointment slips, self-care instructions, and health education brochures (Baker, Williams, Parker, Gazmararian, & Nurss, 1999).

Health literacy is now recognized as an important aspect of health promotion and disease prevention and critical to improving the health of our Nation and its citizens. In the military, limited health literacy may be contributing to disparities in health care utilization and improved health status even though active-duty military personnel have universal access to health care, services and information. Consider, in the context of the culture of the military health system (MHS), gender, race, educational level and income should not impact the availability of health services. The degree to which active duty military personnel are able to obtain health information and services needed to make appropriate health decisions, and improve health status is equal. All active-duty personnel have universal access to health care, and yet, disparities continue to exist in utilization of preventive services and achievement of goals related to improved health status and health outcomes. Although the percentage of military personnel classified as obese (Body Mass Index greater than 30.0) is low compared to the U.S. civilian population (12.4% vs. 31%), military personnel have shown a steady and statistically significant increase in obesity over the past 10 years (up from 8.6% in 2002 to 12.4%) (DoDHA, 2006). Hospitalizations for non battle injuries remain high relative to the Healthy People 2000 objective of 754 injuries per 100,000 ((Total DoD 2635/2679 for 2002/2005 and note that Healthy People 2010 does not specify objective rate and civilian 'imates were not reported). Even with universal access to care, rates of overweight/obesity and hospitalization behind health improvement goals set in Healthy People 2010 (& 2000 for hospitalizations); and even, within a culture that emphasizes health promotion and disease prevention, military personnel do not currently meet health promotion objectives in such areas as blood pressure checks (81.8% vs. 95% objective) and cholesterol checks

(57.2% vs. 80% objective).

To date however, there are no published research studies assessing health literacy in the active-duty military population. Little is known about the degree to which active duty personnel have the capacity to process and understand basic health information, and the subsequent impact of this capacity on health care utilization and proved health status and outcomes. Before studies can be conducted to explore the relationship between limited health literacy and health status/outcomes in active duty personnel, research is needed to determine health literacy rates in active duty personnel and the comparability of these rates to rates in the non-military population. As indicated above, the purpose of this study is to determine health literacy rates in active duty military personnel receiving health care and services within a culture of universal access, and to compare the health literacy rates of non-military populations to those of active duty military.

Specific Aim 1: To identify the literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

The two most widely accepted instruments for measuring health literacy are the Test of Functional health Literary in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM). The shortened version of the S-TOFHLA and the REALM will be used in this study (See Appendix A - Approved full WRAMC protocol with S-TOFHLA and REALM at attachments A & B).

The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages for a total of 36 Cloze items (comprehension skills measured). The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The S-TOFHLA has been shown to have good internal consistency (reliability) (cronbrach's alpha = .68 [4 numeracy items] and .97 [36 Cloze items] for reading comprehension) and concurrent validity compared to the long version of the TOFHLA (r=.91) and the REALM (r=.80). It takes 8-12 minutes to administer (See 'achment A of the WRAMC protocol application for copy of the S-TOFHLA which is selected portions of full .t, development article on S-TOFHLA, and Attachment C of the WRAMC protocol application for information sheet on instruments).

Unlike the S-TOFHLA which measures comprehension (ability to read and understand numbers), the REALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects are asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes by personnel with minimal training and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Attachment B of WRAMC protocol application for copy of REALM and Attachment C of the WRAMC protocol application for information sheet on instruments). The criterion validity for the REALM has been established through correlation with other standardized reading tests at p <0.0001: Pearson Oral Reading Test-Revised (.97); Slosson Oral Reading Test-Revised (.96); and Wide Range Achievement Test (WRAT) reading subtest (WRAT-R) (.88). The REALM has good reliability (test-retest .99) and inter-rater (.99) and as indicated above, is highly correlated with the S-TOFHLA (r=.80). While the S-TOFHLA and REALM have not been used in an active-duty military sample, the instruments have been successfully used in a variety of civilian populations to measure health literacy. Nevertheless, the lack of previous testing in the military and results of the third specific aim should be factors to consider when interpreting the results of this preliminary study.

While the extent of literacy/health literacy has been assessed through the 1992 NALS, 2004 NALS/1992 re-analysis, and the 2003 NAAL (75-million adults with lowest two levels of health literacy skills), these national surveys did not use the TOFHLA or REALM. A review of the literature however, reveals that at least 20 research studies have used the TOFHLA, S-TOFHLA, or REALM to measure the extent of health literacy in civilian pulations. These studies show that limited health literacy skills are common with significant variations in valence depending upon the setting and population sampled (IOM, 2004; Williams et al, 1995; Williams, et al., 1998), e.g., racial or ethnic status, general medical, HIV. These studies also suggest that segments of the U.S. population that could be considered at greatest risk for limited health literacy are those that were reported to have

higher rates of limited literacy in the 1992 NALS (IOM, (2004)) and 2003 NAAL – minorities and lower income individuals.

As indicated above, health literacy skills have not been measured in the active-duty military population even though segments of the population have been identified by IOM (2004) as at risk for limited health literacy such a 'itary recruits. Based on the sociodemographic characteristics (SDC) used in health literacy research with the ..ional population, other segments of the active-duty military population are also at risk of limited health literacy skills, e.g., non Caucasian, and lower ranking personnel (See Appendix A - Approved full WRAMC protocol with SDC data collection sheet at attachment E). Hence, it is critically important to asses the extent of health literacy in the active-duty population.

Specific Aim 2: To examine relationship between limited health literacy skills and gender, race/ethnicity, age, pay grade/rank, education level, and marital status in a sample of active-duty military personnel.

In addition to the national literacy/health literacy surveys, studies using the TOFHLA, S-TOFHLA and REALM have reported a link between limited health literacy and gender, higher rates of hospitalization, lower use of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care costs. Higher rates of limited health literacy have also been also been linked to SDCs such as being non Caucasian, lower education, and/or lower income (IOM (2004), but as indicated above, non of these linkages have been studied in an active-duty military population (See Appendix A - Approved full WRAMC protocol with S-TOFHLA and REALM at attachments A & B).

The SDCs variables of gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) were chosen for this preliminary study because they represent points of comparison between the military and national population (See Appendix A - Approved full WRAMC protocol with SDC data collection sheet at attachment E).

As for specific examples in the literature suggesting a link between limited health literacy and the aforementioned variables in the national population, there are several. For example, in a study by (Arnold et al., ?1) involving smoking status, reading level, and knowledge of tobacco effects in low-income pregnant women, .re was an association between limited health literacy and race (African American). In addition, associations between limited health literacy skills and racial and ethnic status have been identified in studies involving: HIV/AIDs medication adherence (Kalichman et al., 2000); stage of prostate cancer at diagnosis (Bennett et al., 1998) and (Dewalt, Berkman, Sheridan, Lohr, & Pignone, 2004); mediating effects of literacy on race; poorer diabetic outcomes (Schillinger et al., 2002) and cervical cancer screening practices (Lindau et al., 2002). A 2003 study found evidence that there were differences in health literacy status by race (African and Non-African Americans), but noted that much more research is needed because the results may be due to problems with the instrument or more general issues surrounding the assessment of education (Beers et al., 2003). In any event, the most important observation gleaned from the information presented above is the fact that the demographic groups identified in these studies are the same demographic groups identified as being at risk in the 1992 NALS and the reanalysis by Rudd, Kirsch, and Yamamoto (2004). However, as noted in the IOM (2004) health literacy report, none of the studies identified in the field of health literacy thus far, have involved a sufficiently large random sample of adults to allow for full extrapolation to other populations. This preliminary study is an important step in understanding this phenomenon in the context of the active-duty military population.

Additionally, if relationships are found between gender, race/ethnicity, and rank and limited health literacy skills, analysis in this study will progress to the examination of the extent to which gender, race/ethnicity, and rank concepts predict the limited health literacy skills. Health literacy research studies in the national population have demonstrated a relationship between limited health literacy and gender, race/ethnicity, knowledge, health outcomes and socioeconomic status (Bennett et al., 1998; Dewalt et al., 2004; IOM, 2004; Kalichman et al., 2000; Lindau et al., 2002).

'ecific Aim 3: To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty litary personnel.

Like the TOFHLA, the S-TOFHLA was developed and has been used in the national population. To the

researcher's knowledge, the S-TOFHLA has not been used in any published military research studies. The TOFHLA was developed in 1993 and found to be a valid, reliable indicator of patient's ability to read health-related materials (Parker, et al., 1995). Construct validity for the original TOFHLA was ensured by using actual hospital medical texts for both the reading comprehension and numeracy subtexts (Nurss, et al, 1995) while current validity was shown by demonstrating statistically significant correlations between the REALM and the .de Range Achievement Test- Revised (WRAT-R). The WRAT-R is an instrument that has three subtests which measure the codes which are needed to learn the basic skills of reading, spelling, and arithmetic (IOM, 2004). Correlations of the TOFHLA with the REALM and the WRAT-R were .84 and .74, respectively (p<0.001) by Spearman's rank correlation. The REALM and WRAT-R also have a significant correlation of .88 (Parker, et al., 1995).

The S-TOFHLA was developed and tested in 1997 in the same setting used for the development and testing of the TOFHLA – in a sample of 238 patient/subjects from an urban public hospital in Atlanta, Georgia. The results of the testing showed good internal consistency as reflected by a cronbach's alpha of .68 for the 4 numeracy items and .97 for the 36 Cloze items in the reading comprehension section. The correlation between the numeracy score and the reading comprehension score was .60 (Baker, et al., 1999; Williams, et al., 1995). The correlation between the S-TOFHLA and the REALM was .80 (Baker, et al., 1999; Parker, et al., 1995; Williams, et al., 1995). Correlations for subscores of the numeracy and Cloze sections were .61 and .81, respectively. All correlations were significant at p<0.001.

There were however, differences between the S-TOFHLA and the REALM in the mid-range of the tests in that the REALM appeared to overestimate and underestimate subject's reading ability when compared to the S-TOFHLA.. It was suspected that these differences might be due to the fact that some subjects were able to pronounce words correctly, but may still have poor reading comprehension while others may have difficulty pronouncing words in isolation (without the context of other materials on the S-TOFHLA) (Baker, et al., 1999). In any event, the development and testing of the S-TOFHLA provided a short instruments (8-12 minutes to administer) which can aid in the identification of patients who may require special efforts or new health materials to reach their health care goals. It is important therefore, to evaluate whether the instrument is a reliable, valid, and practical tool, e.g., ease
⌐ time of administration, for use in active duty military populations.

OBJECTIVES AND SPECIFIC AIMS

The long-term goal of this study is to explore the relationship between limited health literacy, health care utilization, and improved health status and outcomes. It is hypothesized that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, age, race/ethnicity, and marital status.

The two primary and one secondary specific aims of this study are:

1. To identify the literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional Health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

2. To examine the relationship between limited health literacy skills and gender, race/ethnicity, pay grade/rank, age, education level, and marital status in a sample of active-duty military personnel.

3. A secondary aim of this study is to evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

MEDICAL APPLICATION/ MILITARY RELEVANCE

.he health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, age, race/ethnicity, and marital status (research hypothesis), then universal access to care and services within the MHS might not be enough to overcome disparities in health care

utilization, health status, and health outcomes. New policies and targeted patient/health education strategies may need to be developed and/or implemented to improve health literacy within the active-duty population, before targeted goals for improving health status and increasing use of preventive services can be accomplished. Accordingly, the results of this preliminary study are significant for the Federal government/military because:

Health literacy research has not been conducted in the active-duty military population although limited health literacy has been identified as a national health problem by the Federal government and the Institute of Medicine (IOM) has recommended that Department of Defense (DoD) should focus on the issue of limited health literacy and seek ways to reduce its negative impact within the Military Health System; and

2.   Limited health literacy is related to poorer health status, lower use of preventive services, and overweight/obesity which in the military can lead to a reduction in individual, unit and operational readiness, e.g., loss duty time, less fit force, as well as increased inpatient health care costs when resources are limited due to wartime pressures.

PLAN

Selection of Subjects

Up to 200 subjects enrolled from active-duty personnel who are visiting, working at, or a patient at WRAMC. The use of 200 subjects is to ensure that the sample size is large enough to conduct the analysis being proposed for this study and to account for attrition.

2. Inclusion and Exclusion Criteria

Inclusion Criteria

1. Active duty personnel
2. Willingness to participate and able to read and understand English and answer a questionnaire

b. Exclusion Criteria

1. Blindness
2. Speech impairment
3. Central Nervous System Disorders that effect reading and speaking
4. Unable to give consent

3. Recruitment

Subjects will be recruited from active-duty military personnel who are staff, visitors, or patients at WRAMC using pamphlets and posters placed in the internal/family medicine clinics on Ward 73 at WRAMC (See Appendix A - Approved full WRAMC protocol and Appendix B for advertisement approval). No compensation with be offered to subjects.

4. Consent Process

This study poses no more than minimal risk and does not collect any protected health information outside of the ~ticipant's name obtained on the consent and HIPAA forms. The principal investigator will meet with volunteers obtain written informed consent, explain the study, and answer any questions regarding the concept of health literacy and the study. The dialogue between the investigator team and volunteer will take place in a private office area in WRAMC to ensure confidentiality.

5. Study Methodology /Technical Approach (including the number of subjects to be studied.)

The overall research design for this study is descriptive prospective (Burns & Grove, 2005). The design will ˙de the identification and description of reading grade level (literacy skills) and health literacy skills among .iitary personnel, and the examination of relationships between health literacy skills and gender, rank and race/ethnicity. The design will also provide a platform for evaluating the reliability, validity and practicality of using the S-TOFHLA in a sample of active duty military personnel.

The purpose of this study is to conduct preliminary steps in testing the hypothesis that the health literacy skills in the active-duty military population are similar to the national population according to gender, income as represented by rank/pay grade, and race/ethnicity. Data will be collected at Walter Reed Army Medical Center (WRAMC). To address the potential for selection bias (participants that are in a health related work specialty), we will collect data on whether the participant works in health related field. The target population for this study is active-duty military personnel while the accessible population is active-duty military personnel (military personnel) who are permanent staff, visiting, and/or being treated at WRAMC. The overall research design for this is study is descriptive (Burns & Grove, 2005). The design will guide the identification and description of reading grade level (literacy skills) and health literacy skills among military personnel, and the examination of relationships between health literacy skills and gender, rank and race/ethnicity. The design will also provide a platform for evaluating the reliability, validity and practicality of using the S-TOFHLA in a sample of active duty military personnel.

Consistent with the administration procedures used by researchers to develop the S-TOFHLA, visual acuity will be determined using a pocket vision screener but will not be recorded (Rosenbaum, Graham-Field Surgical Co., Inc. New Hyde Park, NY). Subjects with vision worse than 20/100 will be excluded unless corrected. Those with visual acuity between 20/70 and 20/100 will be given a large print (14 font) version of the S-TOFHLA. These impediments will be assessed through the interview process by the researcher. In addition, speech impairment will be assessed by researcher when discussing participation in the study with potential subject and blindness by ˙servation of potential subject and questioning as to visual acuity – can they read letters of first word in REALM .rectly.

The sociodemographic characteristics used in the second specific aim are based on relationships found in research on health literacy in the national population. The sociodemographic characteristics to be collected are gender, age, race/ethnicity, pay grade/rank, education level, marital status, and to provide context for data analysis, health professional status (See Appendix A - Approved full WRAMC protocol with SDC data collection sheet at attachment E). The findings generated by this preliminary study will be used to: (1) gain a better understanding of health literacy in the active-duty military population; (2) provide information that may be useful in the development and/or revision of Federal agency/military policies and/or patient education materials, and (3) facilitate the development of hypotheses to guide future health literacy research.

Plan for each Specific Aim:

Specific Aim 1: To identify literacy skills (estimated reading grade level) and health literacy skills among a sample of active-duty military personnel using the short version of the Test of Functional health Literary in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).

Rationale. Even though the Federal government has noted that improvements in health literacy will improve health outcomes, better use of preventive services, and weight management and prevent obesity/overweight in the national population, there are no studies focused on health literacy in the active-duty military population. The first specific aim of this study is to describe health literacy skills among a sample of military personnel using the two most widely accepted instruments for measuring health literacy skills – S-TOFHLA and REALM. Comparative ˙fferences between males and females, White, non-Hispanics, & non-Whites and officers & enlisted will be ,essed based on variations in health literacy skills that have been identified in health literacy research and national surveys to date. The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages – (comprehension skills measured)

and can be administered in 8-12 minutes. The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The REALM is a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects will be asked to read from a list of 66 common medical terms t patients would be expected to be able to read in order to participate effectively in their own health care. Each ¸rectly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Appendix A - Approved full WRAMC protocol with REALM at attachment B).

Design and Procedures. The proposal is to be filed with the WRAMC/Department of Clinical Investigations Protocol Coordinator. Approval will also be sought from the USUHS IRB as the principal investigator is a doctoral student in the USUHS/Graduate School of Nursing. After obtaining approval to conduct research at WRAMC and USUHS IRB approval, recruitment will be carried out by placing pamphlets and posters in the common area and clinics at WRAMC. A sample of the pamphlet and poster are included in this protocol for review and approval by the Department of Clinical Investigation (DCI) Protocol Coordinator. Upon approval, the pamphlet and poster will be submitted to the Executive Officer of WRAMC hospital for approval of content and placement with WRAMC.

Working under the guidance of the WRAMC on-site/principal investigator, Col Richard Ricciardi and Dr. Sandra G. Bibb, the Dissertation Chairperson, a private area/room will be identified in which subjects can receive information about the study and health literacy and be tested if they choose to do so voluntarily. Use of this room will ensure confidentiality, minimize outside distractions, and allow the researcher to provide information to subjects on the concept and importance of health literacy. For individuals agreeing to become subjects, the researcher will explain what the instruments are and how they are used. Upon providing informed consent or if waived, upon the provision of a written statement regarding the research, the following SDCs will then be collected along with health professional status: gender, age, marital status, race/ethnicity, and pay grade/rank (See Attachment E of WRAMC protocol application).

Data will be collected from a convenience sample of military members at WRAMC. Data will be analyzed to assess the extent of health literacy and to measure relationships between a subject's health literacy skill level and ¬der, race/ethnicity, marital status, and pay grade/rank.

Data will be kept confidential and only viewed by WRAMC Department of Clinical Investigation officials, principal and associate investigators, USUHS Graduate School of Nursing dissertation committee members and any government agencies as part of their duties such as the Army Clinical Investigation Regulatory Office (CIRO). Data results will be coded and entered into a SPSS spreadsheet by the researcher. Results from the analysis will be used to complete doctoral studies and to facilitate the development of hypotheses to guide future health literacy research. Data will be stored according to WRAMC and USUHS rules and may be used in later research. Consistent with the IOM recommendation for DoD, the results may also provide information that may be useful in the development of effective policies and customized programs that address deficiencies in health literacy skills.

Problems and Solutions. It is estimated that the length of time required for each participant to complete the SDC data sheet, S-TOFHLA and REALM will be 20 minutes (8-12 minutes – S-TOFHLA/2-3 minutes - REALM, respectively). This time period may be too long for some military members to focus on the materials. The solution would be to drop the REALM for those subjects since the S-TOFHLA is the primary health literacy measurement and measures comprehension skills versus decoding skills by the REALM. The loss to the study would be inability to obtain reading grade level for that individual and a smaller sample size to evaluate the reliability, and validity of the S-TOFHLA.

Specific Aim 2: To examine the relationship between health literacy skills and gender, pay grade/rank, age, race/ethnicity, and education level in a sample of active duty personnel.

Rationale. In addition to the national literacy/health literacy surveys, studies using the TOFHLA, S-TOFHLA and REALM have reported a link between limited health literacy and gender, higher rates of hospitalization, lower ¬ of preventive services, poorer health status, overweight/obesity, and higher spending on inpatient health care ¸ts. Higher rates of limited health literacy have also been linked to SDCs such as being non Caucasian, lower education, and/or lower income (IOM (2004), but as indicated above, none of these linkages (correlations and predictive relationships) have been studied in an active-duty military population.

The SDCs variables of gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) were chosen for this preliminary study because they represent points of comparison between the military and national population (See Appendix A - Approved full WRAMC protocol with SDC data collection sheet at attachment E). The rationale and instruments used to measure health literacy skills are the same as for the first cific aim.

_oblems and Solutions. Same as indicated above in the first specific aim.

As appropriate, the study design and methodology should include the following sub-sections:

Table 1.   ɔles, Measures (Level of Data), and Analytic Approach

Variable Name	Nominal	Ordinal	Scale	Specific Aim(s) and Analytic Approach
Health Literacy	S-TOFHLA - Adequate & Inadequate (Marginal & Inadequate Combined using S-TOFHLA REALM -Adequate & Inadequate (Reading level <9th grade)	S-TOFHLA – 3 groupings -Inadequate -Marginal -Adequate REALM – 4 groupings -3rd and below -4th – 6th -7th – 8th -9th and above	S-TOFHLA -Score range = 1-100 REALM -Score range = 1-66	Aim 1 -Univariate statistics = measures of tendency, frequency distributions, categorical groupings of S-TOFHLA and REALM -Independent samples t test, ANOVA, Chi Square for comparing groups -Mann-Whitney, Phi & Fisher's Exact if appropriate for data to compare groups Aim 2 -Pearson's product moment correlation, Spearman's rank order correlation, and Chi Square to assess relationships Between SDCs (independent Variables (IVs) and test(s) (dependent Variables (DVs)) -Multiple linear regression and logistic regression, as appropriate Aim 3 -Cronbach's Alpha, Pearson's product Moment correlation, and Spearman's rank order correlation to assess reliability and validity of S-TOFHLA and REALM, respectively.
Sociodemographic Characteristics	Marital status ---Single, never married ---Married, living together ---Separated ---Widowed	Education -Did not graduate from high school -GED certificate -High School Diploma -Some college, but not 4-year college degree or higher	Age in years	Aim 1 -Univariate/Descriptive statistics -As IVs, the SDCs will be used to run independent samples t tests and ANOVAs with S-TOFHLA and REALM (as DVs) to compare groupings Aim 2 Same as Aim 2, above

Specific Aim 3. To evaluate the reliability, validity, and practicality of the S-TOFHLA in a sample of active-duty military personnel.

Rationale. Health literacy skills have not been studied in the active-duty military population. The S-TOFHLA .il be used to conduct this study along with the REALM. To assess whether the S-TOFHLA is an appropriate instrument for measuring health literacy skills in the military, the reliability, validity, and practicality of the instrument will be evaluated based on the data collected.

Problems and Solutions. Same as indicated above in the first specific aim.

Conceptual Framework

An extensive review of the literature reveals that numerous theories have been used to study the concept of health literacy. Doak, Doak and Root (1996) identified a number of these theories such as the health belief model, trans-theoretical model, social cognitive theory (SCT), and diffusion theory. None of these frameworks however, focus specifically on health literacy. Zarcodoolas, Pleasant, and Greer (2005) recently proposed a multi-dimensional health literacy model which focuses on four central literacy domains; fundamental, science, civic, and cultural. To date, this model has not used to guide published research.

Using the definition of health literacy formulated by the National Library of Medicine and used in Healthy People 2010, the IOM also developed a multi-dimensional health literacy model known simply as the Health Literacy Framework (HLF). The HLF focuses on the three sectors which assume responsibility for health literacy: culture and society, health system, and education system. These sectors provide intervention points for improving an individual's health literacy regardless of an individual's status and/or health system (IOM, 2004). This adaptability makes the HLF ideal for conducting health literacy research in the active-duty military population.

The HLF will be used to guide this preliminary study because as adapted, the HLF represents the theoretical interaction of military members with the three key sectors of health literacy and intervention points: educational ·tems, health care systems, and cultural/societal factors. Within this non-causal framework, literacy is the .ndation for health literacy and provides the starting point for understanding and communicating health information and concerns. Health literacy is the bridge or active mediator(s) between military members and health contexts – situations and activities relating to health. Although associations between health literacy and health outcomes and costs have not been conclusively established, research findings suggest such a strong relationship between the concepts (IOM, 2004). As this is the first study on health literacy within the active-duty military population, this study will focus on the concepts of literacy and health literacy.

A visual depiction of the HLF is provided in Diagram 1, below. The diagram shows the essential framework for considering health literacy including the interaction(s) and relationship(s) between the three key sectors and intervention points for improving health literacy skills. Below this diagram, Table 3 sets forth a list of variable names, conceptual definitions, operational definitions, and corresponding measures, contained in the HFL

Diagram 1. Health Literacy Framework

Potential Intervention Point for Improving Health Literacy
Culture/Society (Military) – Health System (MHS) – Education (MHS Programs)

Health Contexts
(Culture/Society – Health System – Education

HEALTH LITERACY

Individual/Military Member

LITERACY

Health Outcomes, e.g., overweight/ obesity & $$$ = Increased Health and Cost Savings
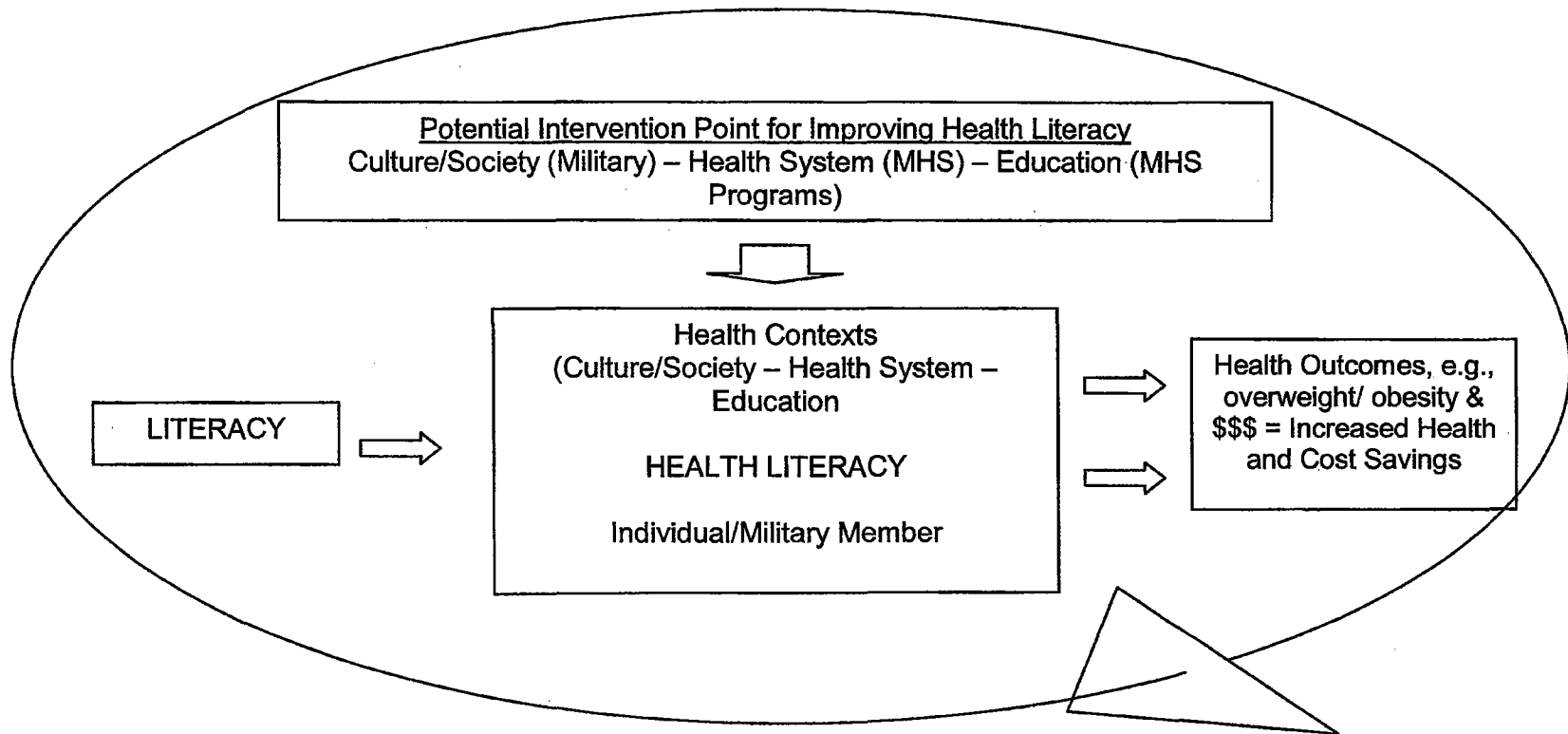
Table 3. H.. .in Literacy Framework, Variables, Definitions, and Applicab.. .easures

Variable Name	Conceptual Definition	Operational Definition	Measure
Literacy	Constellation of skills including reading, writing, basic , numeracy, & speech/speech comprehension in specific contexts [prose, document and quantitative] (Kirsch, 2001)	The grade reading level (or reading difficulty level)(literacy skills) - in the health context, the ability to read at the 10th grade level or above.	- REALM – Estimated Reading Grade Level
Health Literacy	Degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions	Subjects ability to read and under the things they commonly encounter in the health care setting	- S-TOFHLA - overall assessment of health literacy - REALM – decoding measurement of adult literacy in medicine for adults
Health Context (HC) & Intervention Points			
HC/IP – Culture & Society	Shared ideas, meanings, and values acquired by individuals as members of society. Includes social determinants of health such as native language, SDCs, along with influences of mass media and the plethora of health information sources available through electronic sources	SDCs - Gender, Marital Status, Race/Ethnicity, and Pay grade/ Rank plus health professional status	-Gender -Age -Rank/Pay grade -Race/Ethnicity -Marital Status -Education level -health professional train status (RN, medic, etc.) -Financial and structural access to care (MHS) -Deployed personnel -Policies mandating physical fitness

HC/IP Health Syst	Refers to all people performing health related activities including those working in hospitals, clinics, offices, home health care, public health agencies, regulatory agencies, insurers,& accreditation groups	Military Health System – Program materials used in MHS and sample of military members who use MHS	Not being measured
HC/IP Education System	The education system in the United States 12), adult education programs and higher education along with formative and continuing education for health professionals	MHS patient education programs and health professional training including military Schools	Not being measured
Health Outcomes Costs)	Improvements in health status and/or cost savings but varies because contextual to person or health system being analyzed	Overweight/obesity, $$, knowledge of disease, healthy heart practices, and any other health outcome or monetary measurement	Not being measured

6. Data Collection and Statistical Considerations

The investigative team will collect data in a private area/room located in the internal/family medicine clinic at ./RAMC. After informed consent is obtained, the following sociodemographic data will be collected: health professional training status: gender, age, marital status, race/ethnicity, and pay grade/rank. Volunteers will then be asked to take the S-TOFHLA and REALM.

Data will be collected from a convenience sample of military members. Each study participant will be asked to participate in one session lasting approximately 20 minutes. Data results will be coded and entered into a SPSS spreadsheet by the researcher.

Overview of Measurement Instruments used in Data Collection

The two most widely accepted instruments for measuring health literacy are the Test of Functional health Literary in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM). The shortened version of the S-TOFHLA and the REALM will be used in this study (See Appendix A - Approved full WRAMC protocol with S-TOFLA and REALM at attachments A & B).

The S-TOFHLA measures a patient's ability to read and understand actual health texts and consists of 4 numeracy items (quantitative literacy) and 2 prose passages for a total of 36 Cloze items (comprehension skills measured). The results are scored on a scale from 1-100 and can be classified in one of three ways: inadequate health literacy (score of 0-53); marginal health literacy (score of 54-66); and adequate health literacy (score of 67-100). The S-TOFHLA has been shown to have good internal consistency (reliability) (cronbrach's alpha = .68 [4 numeracy items] and .97 [36 Cloze items] for reading comprehension) and concurrent validity compared to the long version of the TOFHLA (r=.91) and the REALM (r=.80). It takes 8-12 minutes to administer (See Attachment A of WRAMC protocol application for copy of S-TOFHLA)..

Unlike the S-TOFHLA which measures comprehension (ability to read and understand numbers), the REALM a medical-word recognition test (decoding skills) for screening adult reading ability in medical settings. Subjects are asked to read from a list of 66 common medical terms that patients would be expected to be able to read in order to participate effectively in their own health care. Each correctly read and pronounced work increases a subject's score by 1. The REALM can be administered and scored in 2-3 minutes by personnel with minimal training and the scores can be converted into four reading grade levels: 0-3; 4-6; 7-8 and 9 and above (See Attachment B of WRAMC protocol application for copy of REALM). The criterion validity for the REALM has been established through correlation with other standardized reading tests at p <0.0001: Pearson Oral Reading Test-Revised (.97); Slosson Oral Reading Test-Revised (.96); and Wide Range Achievement Test (WRAT) reading subtest (WRAT-R) (.88). The REALM has good reliability (test-retest .99) and inter-rater (.99) and as indicated above, is highly correlated with the S-TOFHLA (r=.80). While the S-TOFHLA and REALM have not been used in an active-duty military sample, the instruments have been successfully used in a variety of civilian populations to measure health literacy. Nevertheless, the lack of previous testing in the military and results of the third specific aim will be factors to consider when interpreting the results of this preliminary study.

Data analysis

We will describe data analysis specific to each of the study aims:

Specific Aim 1: Data will be collected at the nominal, ordinal, and scale level. Univariate statistics (frequency distributions, measures of central tendency, categorical groupings of literacy level, e.g., estimated reading level, marginal health literacy) will be used to describe SCDs, health professional status, and health literacy skills among active duty military personnel. The S-STOFHLA scores and standard cutoffs will be used to estimate the .oportion of the sample with adequate and inadequate functional health literacy skills. Average scores will be compared across demographic subgroups using a two group (male and female) (independent) t-test and/or ANOVA.

Specific Aim 2: Data will be collected as indicated above and at the nominal, ordinal and scale level. Pearson's product moment correlation will be used to explore the strength of the relationship between two continuous variables such as the S-TOFHLA and REALM, and S-TOFHLA and age in years. Multiple linear regression will be used to describe joint relationships where the dependent variable is the S-TOFHLA score as continuous variable 1 the independent variables are the SDCs. Categorical independent variables will be dummy coded for inclusion ...r the multiple linear regression model if relationships suggest performing predictive analysis. Independent samples Chi square will also be used to examine relationships between health literacy skills and categorical variables -- gender, race/ethnicity (White, non-Hispanic, & non-White), and rank (officer & enlisted) and predictive analysis will be conducted using logistic regression as appropriate.

Specific Aim 3: The instruments used to measure health literacy are the same as the previous two specific aims. Cronbach's Alpha will be used to assess reliability (internal consistency) of the S-TOFHLA on the numeracy and Cloze items and a correlation between the two sections determined. Then, the correlation between the REALM and the total scores for the S-TOFHLA, the total score for the numeracy items and the total score for the Cloze items will be assessed with the Pearson's product moment correlation. Spearman rank correlation coefficient will also be used to compare the three S-TOFHLA categories and the four categories of the REALM.

Sample Size Estimation

The statistical power and sample-size estimation were powered on the associations (gender) proposed for this preliminary study and were established with collaboration with the DoD/USUHS biostatistician. After discussion, a sample size of 200 was decided upon to ensure that the sample size is large enough to conduct the analysis proposed for this study and account for attrition. As this is a preliminary study, the power analysis was determined a need for a sample size of 150. With 150 subjects, a two group t-test with a .05 two-sided significance level will have .80 power to detect a difference of 11.5 points on the S-TOFHLA when the sample sizes in the two groups are 30 and 120 respectively, assuming the standard deviation of S-TOFHLA scores is 20. It is estimated that 20% of ɔ sample will be female. This sample size will yield a margin of error of 7.3 percentage points for estimating the _.evalence of "inadequate" health literacy skills, assuming a .95, 2-sided confidence interval and a prevalence of .30.

7. Study Time Line -

Table 2. Timing Sequence:

Timeline	Oct 07	Nov 07	Dec 07	Jan 08	Feb 08	Mar 08	Apr 08	May 08	Jun 08	July 08	Aug 08	Sept 08	Oct 08	Nov 08			
Obtain IRB approvals	■																
Subject Recruitment			■	■	■												
Data Collection			■	■	■												
Data Analysis						■	■										
Dissemination								■	■	■	■	■					

Reporting Adverse Events

'r sponsored studies, reference the appropriate pages of the sponsor protocol for adverse events report.)

Definitions:
Adverse events (adverse effects, adverse reactions): any occurrence of injury, dysfunction, disease, or abnormality of any organ or tissue that occurs in a subject enrolled in a clinical protocol. Manifestations of an adverse event may include symptoms, physical exam abnormalities, diagnostic study abnormalities, and/or death.

Expected adverse events: adverse events previously known or anticipated to result from: 1) the interventions and interactions used in the research (these events must be included as potential risks in the consent form); 2) the collection of identifiable private information under research (these events must be included as potential risks in the consent form); 3) an underlying disease, disorder, or condition of the human subjects; and/or 4) other circumstances unrelated to the research or any underlying disease, disorder, or condition of the subject.

Unexpected adverse events /Unanticipated problems: adverse events that 1) are not expected given the nature of the research procedures and the subject population being studied; and 2) suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

Serious adverse event: an adverse event that is fatal, life-threatening, permanently disabling, require inpatient hospitalization, or result in congenital anomalies/birth defect, overdose or cancer.

Expected Adverse Events from Research Risks and Reporting

.ere are no expected risks or discomforts anticipated with this study. However, any serious and unexpected adverse events will be reported to the Human Use Committee in accordance with the Department of Clinical Investigation procedure.

The principal investigator (PI) will, within one working day, report any serious adverse events WRAMC to the Human Use Committee (HUC) by submitting an adverse event report memorandum to the HUC via DCI. Serious adverse events will be reported even if the PI believes that the adverse events are unrelated to the protocol.

Unexpected (but not serious) adverse events occurring in subjects enrolled at WRAMC which, in the opinion of the PI, are possibly related to participation in the protocol will be reported by the PI within 10 (ten) working days to the HUC using the same procedure and to the USU IRB as indicated in the next section.

Expected adverse events which are not serious will also be reported on the Continuing Review Report (USU Form 3204A) during the continuing review of the protocol and the principal investigator will also follow the procedures listed in the next section.

Reporting Serious and Unexpected Adverse Events to the IRB

Serious Adverse Events: The PI, within 48 hours, must report all serious adverse events (SAE) occurring in enrolled subjects. This is accomplished by submitting an adverse event report memorandum to the IRB office. For protocols involving investigational drugs or devices, the investigator must also report a serious adverse
ent to the sponsor of the IND or IDE immediately (within 24 hours). Serious adverse events must be reported
en if the PI believes that the adverse events are unrelated to the protocol.

Unexpected (but not serious) adverse events occurring in subjects, which, in the opinion of the PI, are possibly

related to participation in the protocol must be reported by the PI within 10 (ten) working days to the IRB using the same procedure.

For all serious and/or unexpected adverse events, the PI must forward a copy of the adverse event report to the dical Monitor for the protocol.

For multi-center studies, unexpected or serious adverse events occurring in subjects enrolled at other medical facilities must be reported to the IRB within 10 working days after the PI receives notification of such events.

A summary of all serious or unexpected side effects also must be included in the 3204A.

Human Biological Specimens/Tissue (HBS/tissue).

Not Applicable

Subject Confidentiality Protection

Not applicable. All participants will be active-duty members of the Armed Forces.

HIPAA Authorization, if applicable
Your answers to the following questions will assist compliance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA).

If your research will collect Protected Health Information (PHI) such as, physical, clinical, psychological well-being, behavioral and genetic data (e.g., blood pressure, type of cancer, disease stage, ADL, PSA, urine protein, use of alcohol, depression, etc.) **along** with any of the following 18 personal identifiers, a HIPAA authorization is uired. The research data collected in such format is referred to as "Identifiable Protected Health Information"

     i. Are you intending to collect subject's Protected Health Information (PHI) and any of the following 18 personal identifiers?
        ___ No – HIPAA does not apply – go to question #**iv** .
        _X_ Yes – please check which ones:

(See Appendix A - Approved full WRAMC protocol and Appendix C and D for WRAMC approved HIPPA form and informed consent form)

    _X_ 1. Names Via Informed Consent Form
    ___ 2. Street address, city, county, 5-digit zip code
    ___ 3. Months and dates (years are OK) and ages >89 (unless all persons over 89 years are aggregated into a single category)
    ___ 4. Telephone numbers
    ___ 5. Fax numbers
    ___ 6. E-mail addresses
    ___ 7. Social security number
    ___ 8. Medical record number
    ___ 9. Health plan beneficiary number
    ___ 10. Account number
    ___ 11. Certificate/license number
    ___ 12. Vehicle identification number (VIN) and/or license plate number
    ___ 13. Device identifiers and serial numbers
    ___ 14. URLs (Uniform Resource Locators)
    ___ 15. Internet protocol address number
    ___ 16. Biometric identifiers, such as finger and voice prints
    ___ 17. Full face photographic images or any comparable images
    ___ 18. Any other unique identifying number, characteristic, or code such as patient initials

ii. Can you limit your collection of personal identifiers to just dates, city/state/zip, and/or "other unique identifier" (#18 of the above)?

___ Yes – then your dataset may qualify as a Limited Data Set – please complete a Data Use Agreement and attach to your protocol. Then go to question #iv.

___ No – Go to question #iii.

iii. Is obtaining patient Authorization "impracticable"?

___ Yes – Authorization may qualify to be waived by the IRB. Go to section 6.7.3 HIPAA Authorization Waiver for the application.

___ No – Research subjects will need to sign a HIPAA Authorization. Complete the HIPAA Authorization and attach to this protocol.

iv. What precautions will you take to protect the confidentiality of research source documents (Case Report Forms, questionnaires, etc.), the research data file, and the master code (if any)?

Identifying information such as name and date of birth will be removed from the REALM collection sheet. However, the subject's name will be collected on the informed consent form. All data will be collected by the associate investigator. The sociodemographic data sheets (Attachment E of WRAMC protocol application) and study results will be collected by the associate investigator at the time of testing and secured in a locked area in Building 1, Room A251, WRAMC, in accordance with the rules of WRAMC DCI and the DoD/Uniformed Services University of Health Sciences (USUHS). Information from the collected data sheets and tests will be entered into a desktop computer to be maintained by the study investigators. Data will be kept confidential and only viewed by the investigative team, WRAMC Division of Clinical Investigation officials, USUHS Graduate School of Nursing dissertation committee members.

v. When will you destroy the research source documents, data file, and the master code?

vi. Will research data including Identifiable Protected Health Information be sent outside?

___ Yes – Please explain assurances you have received from the outside party that they will appropriately follow confidentiality protections, follow the HIPAA requirements, and abide by the provisions of your Authorization.

_X_ No

HIPAA Authorization Waiver

Not applicable.

Reporting Protocol Deviations

All protocol deviations during the course of the study will be promptly reported to the USU IRB office and WRAMC IRB office, if apppliacble.

Reporting protocol deviation is accomplished by submitting a protocol deviation memorandum to the IRB.

REFERENCES

1. Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. . (2006). *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy.*
   Dictionary.Com. (2006). Literacy. from http://dictionary.reference.com/search?q=literacy
   Selden, C. R., Zorn, M., Ratzan, S., & Parker, R. M. (2000). *National Library of Medicine Current Bibliographies in Medicine: Health Literacy (NLM Pub. No. CBM 2000-1).* Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health.

4. IOM. (2004). *Health Literacy: A Prescription to End Confusion.* IOM (Institute of Medicine). Washington, D.C.: The National Academies Press.

5. Simonds, S. K. (1974). Health Education as Social Policy. *Health Education Monogram* 2, 1-25.

   HHS. (2000). *Healthy People 2010: Understanding and Improving Health.* Retrieved. from http://www.healthypeople.gov/Document/tableofcontents.htm#Volume2.

7. Zorn, M., Allen, M. P., & Horowitz, A. M. (2004). *National Library of Medicine Current Bibliographies in Medicine: Understanding Health Literacy and its Barriers. (NLM Pub. No. CBM 2004-1).* Bethesda, MD: U.S. Department of Health and Human Services/National Institutes of Health

8. Tones, K. (2002). Health literacy: new wine in old bottles? *Health Educ. Res., 17*(3), 287-290.

9. Kirsch, I. S., Jungeblut, A., Jenkins, L., & Kolstad, A. (2002). *Adult Literacy in America: A First Look at the Results of the National Adult Literacy Survey (3rd ed).* Washington, D.C.: U.S. Department of Education: National Center for Education Statistics.

10. Parker. (2000). Health literacy: a challenge for American patients and their health care providers. *Health Promot. Int., 15*(4), 277-283.

11. Rudd, R., Kirsch, I., & Yamamoto, K. (2004). *Literacy and Health in America: Policy Information Report.* Princeton, NJ: Educational Testing Service.

12. Baker, D. W., Williams, M. V., Parker, R. M., Gazmararian, J. A., & Nurss, J. R. (1999). Development of a brief test to measure functional health literacy. *Patient Educ Couns, 38*(1), 33-42.

13. DoDHA (2006). Department of Defense 2005 Survey of Health Related Behaviors Among Active Duty Miltiary Personel. Prepared by RTI International, December 2006.

14. Williams, M. V., R. M. Parker, et al. (1995). "Inadequate functional health literacy among patients at two public hospitals." JAMA, 274(21): 1677-82.

15. Williams, M.V., Baker, D.W., Honig, E.G., Lee T.M., & Nowlan, A. (1998), Inadequate literacy is a barrier to asthma knowledge and self-care. Chest, 114(4).

16. Kalichman, S. C., Benotsch, E., Suarez, T., Catz, S., Miller, J., & Rompa, D. (2000). Health literacy and health-related knowledge among persons living with HIV/AIDS. *Am J Prev Med, 18*(4), 325-331.

17. Bennett, C. L., Ferreira, M. R., Davis, T. C., Kaplan, J., Weinberger, M., Kuzel, T., et al. (1998). Relation between literacy, race, and stage of presentation among low-income patients with prostate cancer. *J Clin Oncol, 16*(9), 3101-3104.

18. Dewalt, D. A., Berkman, N. D., Sheridan, S., Lohr, K. N., & Pignone, M. P. (2004). Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med, 19*(12), 1228-1239.

19. Lindau, S. T., Tomori, C., Lyons, T., Langseth, L., Bennett, C. L., & Garcia, P. (2002). The association of health literacy with cervical cancer prevention knowledge and health behaviors in a multiethnic cohort of women. *Am J Obstet Gynecol, 186*(5), 938-943.

20. Beers, B. B., McDonald, V. J., Quistberg, D. A., Ravenell, K. L., Asch, D. A., & Shea, J. A. (2003). Disparities in Health literacy between African American and non-African American Primary Care Patients. *Abstract. Journal of General Internal Medicine, 18 (Supplement 1),* 169.

21. Parker, R. M., D. W. Baker, et al. (1995). "The test of functional health literacy in adults: a new instrument for measuring patients' literacy skills." J Gen Intern Med 10(10): 537-41.

22. Arnold, C.L., Davis, T.C., Berkel, H.J., Jackson, R.H., Nandy, I., & London, S. (2001). Smoking status, reading level, and knowledge of tobacco effects among low-ijncome pregnant women. Prev. *Med., 32*(4), 313-320.

23. Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., et al. (2002). Association of Health Literacy with Diabetes Outcome. *JAMA, 288*(4), 475-482.

24. Burns, N., & Grove, S. K. (2005). *The practice of nursing research: conduct, critique, and utilization* (5th ed.). St. Louis, MO: Elsevier

FACILITIES/ORGANIZATIONS TO BE USED

Internal/family medicine clinics on Ward 73 at Walter Reed Army Medical Center.

..PPENDICES

Appendix A - Full approved protocol by WRAMC which includes all attachments referenced in USU Form 3204, CITI training certificate, pamphlet/poster design, and licenses/permissions to use S-TOFHLA and REALM.

Appendix B – Approval letter for WRAMC advertisement

Appendix C – Approved WRAMC HIPPA form

Appendix D – Approved WRAMC informed consent form